ATTACHMENT 3c. CCDE Data Users Manual

|  |
| --- |
| Form Approved OMB# 0920-0745 Expiration 6/30/2013SFL_Logo_Control_Program_Horiz_RGBColorectal Clinical Data Elements (CCDE)DATA USER'S MANUALfor theColorectal Cancer Control Program (CRCCP)CCDE Version 1.00March 2010Centers for Disease Control and PreventionNational Center for Chronic Disease Preventionand Health PromotionDivision of Cancer Prevention and ControlPublic reporting burden of this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-24, Atlanta, GA 30333. |

**Introduction**

This manual was written by the Centers for Disease Control and Prevention (CDC) to centralize the information needed to produce data for the Colorectal Cancer Control Program (CRCCP). One goal of the manual is to provide the technical information necessary for the grantees to produce the Colorectal Cancer Clinical Data Elements (CCDEs). Another goal is to highlight the technical assistance provided to the grantees by the CDC and the clinical data contractor, Information Management Services, Inc. (IMS). A common goal of the CDC and the grantees is to produce data that are timely, complete, and of high quality so that we can better serve the clients targeted by the program.

The intended audience for this manual is the grantee staff responsible for the collection and aggregation of the CCDE data. It is divided into 4 chapters as follows:

Chapter 1 **Data Submission**

This chapter contains the dates that the Colorectal Cancer Clinical Data Elements (CCDEs) are to be submitted to IMS, along with the technical requirements for submission.

Chapter 2 **Colorectal Cancer Clinical Data Elements (CCDEs)**

This chapter includes a general introduction to the CCDEs and detailed information about each CCDE data item.

Chapter 3 **Registry Linkage**

This chapter provides variable definition tables that outline each of the collaborative stage variables collected in the CCDEs.

Chapter 4 **References**

This chapter contains the appendices to the manual including the CCDE Submission Narrative Guidelines, the CDC Race and Ethnicity Code Set, the CCDE Data Definition Table, and a Glossary of Terms.

**Chapter 1** **CCDE Data Submission**

[What](#Subm_what) 1

[When](#Subm_when) 1

[How](#Subm_how) 2

[Updates and Corrections](#Subm_updates) 2

[Edits Program](#Subm_edits) 2

[Submission Narrative](#Subm_narr) 2

[Submission Narrative Standards](#Subm_narr_standrds) 3

[IMS and the CCDEs](#Subm_IMS) 3

[CCDE Data Submission Process](#Subm_process) 4

[Software Selection](#Subm_software) 5

**Chapter 2 Colorectal Cancer Clinical Data Elements (CCDEs)**

###### [Introduction to the CCDE Chapter](#IntroductionCCDEChapter) 9

 Understanding CCDE Data

[Colorectal Cancer Clinical Data Elements](#CH2_UnderstandingCCDE) 13

[CCDE Cycle Definition](#CycleDef) 13

[Structure of the CCDEs](#CCDE_Structure) 13

[Race and Hispanic Origin](#Race) 15

[Unique Client Identifier](#UniqueID) 15

[Data Conventions](#DataConventions) 16

CCDE Field Descriptions

[Section 1](#section1) Client and Record Identification 19

[Section 2](#section2) Demographic Information 24

[Section 3](#section3) Screening History 35

[Section 4](#section4) Assessed Risk 36

[Section 5](#section5) Screening Adherence 41

[Section 6](#section6) Screening and Diagnostic Tests Performed 44

[Section 7](#section7) Pathology from all Endoscopy Tests Performed 101

[Section 8](#section8) Diagnosis Information for Surgeries Performed to
 Complete Diagnosis 108

[Section 9](#section9) Final Diagnosis 111

[Section 10](#section10) Treatment Information 125

[Section 11](#section11) Registry Information for Cancer/High Grade Dysplasia 130

[Section 12](#section12) Record Information 141

**Chapter 3 Registry Linkage**

[CCDE Item 11.03](#RL_1103) Registry Histologic type 147

[CCDE Item 11.04](#RL_1104) Registry behavior 146

[CCDE Item 11.05](#RL_1105) Registry primary site 156

[CCDE Item 11.06](#RL_1106) Registry CS-derived SS2000 160

[CCDE Item 11.07](#RL_1107) Registry CS-derived AJCC stage group 161

[CCDE Item 11.08](#RL_1108) Registry CS extension 162

[CCDE Item 11.09](#RL_1109) Registry CS lymph nodes 168

[CCDE Item 11.10](#RL_1110) Registry CS mets at diagnosis 171

**Chapter 4 References**

[Appendix A](#AppendixA) – CCDE Submission Narrative Guidelines 178

[Appendix B](#AppendixB) – CDC Race and Ethnicity Code Set 184

[Appendix C](#appendixC) – CCDE Data Definition Table 190

[Appendix D](#appendixD) – Glossary of Terms 218

**CHAPTER 1**

**CCDE Data Submission**

**What:** CCDE data are submitted semi-annually to IMS. Each CCDE submission will include cumulative data from the beginning of screening through the submission’s ***screening cut-off date***, which is 2.5 months prior to the due date. Do not include records dated after the screening cut-off date. The 2.5 month lag time between the cut-off date and the reporting of the CCDE data will allow time to collect and perform quality control on these data. Submitted records may have incomplete data that will be updated on a subsequent submission. Each submission dataset will replace the previous submission in its entirety.

***Screening Cut-off Date:*** CCDE Item 5.1 (Initial test appointment date, or date fecal kit distributed) should be used as the screening cut-off date to determine if the record should be included in the submission. Item 5.1 represents the date that screening was initiated for clients enrolled in the program, regardless of whether testing was completed or not. Refer to Chapter 2 for more information on tracking screening adherence in the CCDEs.

For example, if the data are due to IMS on 09/15/2010, the data should cover all records indicating procedures initially scheduled or fecal kits distributed (CCDE Item 5.1) from the onset of the screening program through 06/30/2010.

***Inclusion of records:***

The CCDE data file should contain records on all clients who were enrolled in the Colorectal Cancer Control Program (CRCCP) and who received services paid for using CDC funds. This includes clients who are determined to be eligible and are scheduled for screening procedures or given a take-home fecal kit, regardless of whether they return the kit or adhere to screening.

If authorized by CDC, records of clients screened using other non-CRCCP funding sources may be reported, but should be limited to publically funded screening of a similar eligible population.

**When:** CCDE data are submitted to IMS according to the schedule below.

All files should be received by IMS by close of business on the due date. If the submission due date falls on a weekend or holiday, then the data should be received by the close of business on the first business day after the submission due date.

|  |  |
| --- | --- |
| **Submission Due** | **Screening Cut-off Date** |
| 09/15/2010 | 06/30/2010 |
| 03/15/2011 | 12/31/2010 |
| 09/15/2011 | 06/30/2011 |
| 03/15/2012 | 12/31/2011 |
| 09/15/2012 | 06/30/2012 |
| 03/15/2013 | 12/31/2012 |

**How:** When a CCDE submission is due, the CCDE data must be extracted from your client database and put into the standardized CCDE format. The CCDE file consists of fixed length records in an ASCII file format. In Version 1.00 of the CCDE data file format, each record consists of 526 columns which includes 524 columns for reporting screening, diagnosis, treatment and Cancer Registry information and a 2 character end-of-record delimiter in the form of a "carriage return-line feed". A detailed description of the CCDE items in each record is included in Chapter 2.

The CCDE file must be submitted electronically using the secure [www.CRCCP.org](http://www.crcsdp.org) Web site. IMS and the CDC require the use of compression software such as WinZip or Gzip to compress the CCDE data file prior to submission.

It is necessary for each grantee to name their CCDE file using the following naming convention:

YP -> Your Program’s abbreviation (e.g. AL = Alabama)

MM -> Month of submission due date, with leading zeroes (09 = September)

YY -> Year of submission due date (10 = 2010)

VVV -> CCDE version number (100 = CCDE version 1.00)

For example, the compressed file that Alabama submits to IMS for the September 2010 submission will have the following name: AL0910100.zip or AL0910100.gz. The WinZip or Gzip file would contain an ASCII file called AL0910100.txt. Please do not include other files, such as the Submission Narrative or other supporting documents in the CCDE zip file. Those files should be submitted separately.

**Updates and Corrections:** For each CCDE submission, grantees are required to submit a cumulative data set through the screening cut-off date. Therefore, if any changes or updates to a particular record occur between CCDE submissions, these changes will be incorporated within the next CCDE data file.

**CCDE Edits Program:** IMS will develop an edits program for grantee use that should be used to evaluate the CCDE data file prior to each CCDE submission. The edits program will perform basic validation routines and report on invalid values, missing fields, and cross-field edits. The edits program and further instructions on its use will be provided via the [www.CRCCP.org](http://www.crcsdp.org) Web site.

**Submission Narrative:** A Submission Narrative should be provided with each data submission. CCDE data are regularly reviewed by the CDC, IMS, and grantee staff. Often questions arise from these reviews, and sometimes these questions lead to modifications to the CCDE data and/or its processing. The Submission Narrative provides a structured way for grantees to report responses to these questions or to report the details of data modifications.

The Submission Narrative has two sections. Section I is where responses to Action Items (written questions from the CDC and IMS based on a data review conference call) are provided. Section II is comprised of five standard questions that require grantees to do a prospective review of their CCDE data prior to submitting it to IMS. A hard copy of the CCDE Submission Narrative Guidelines can also be located in [Appendix A](#AppendixA). An electronic copy may be found on the [www.CRCCP.org](http://www.crcsdp.org) Web site. A response to each of the five standard questions is required in the Submission Narrative, even if that response is “N/A - Not applicable”. It is expected that grantees should have the capability to review and manage their data, and should not rely solely on the CCDE submission feedback provided by CDC and IMS.

**Submission Narrative Standards:** The narrative file should be created in \*.doc or \*.pdf format and submitted using the following naming convention:

*YPMMYY-NARRATIVE*

YP = Your Program’s abbreviation (e.g. AL = Alabama)

MM = Month of submission due date, with leading zeroes (09 = September)

YY = Year of submission due date (10 = 2010)

For example, the submission narrative file that Alabama submits to IMS in \*.doc format for the September 2010 CCDE submission will have the following name: AL0910-narrative.doc. The narrative file should be submitted separately from the CCDE data zip file.

**IMS and the CCDEs:** Once these CCDE data are received at IMS they are reviewed and validated. Using SAS, listings and printouts of sample records for each grantee are produced to check data quality. A SAS analysis file is created that attempts to clean up invalid data and eliminate duplicate screening results. A series of reports are then generated to assess the completeness and accuracy of these data, as well as to document the percentage of abnormal screening results that have complete diagnostic and treatment data. These data are assessed to determine progress in meeting program goals.

**Semi-annual CCDE Data Submission Process**

**Grantees**

**CCDE file (Cumulative data)**

There are six steps in the CCDE Submission Process that repeat semi-annually:

**Reports, data reviews, and conference calls with CDC/IMS**

**Submission Narrative**

**National and Grantee Specific Reports**

**Validation and Analysis**

**IMS**

[**www.crccp.org**](http://www.crccp.org) **Web site**

**Export**

|  |
| --- |
| **CCDE Submission Process** |
| **Semi-annual Timeline** | **Steps** |
| **March** | **September** | **Grantee programs prepare and submit a CCDE file** and Submission Narrative on March 15 and September 15. |
| **May** | **November** | **IMS creates an analysis file** that is provided to the CDC, within a specified time frame, for review and approval. |
| **June** | **December** | **IMS generates feedback reports** which are reviewed and posted to the [www.crccp.org](http://www.crccp.org) Web site within a specified time frame. |
| **July** | **January** | CCDE **Data Review Calls are held** within approximately one month of the posting of the feedback reports. Data Notes, prepared by the IMS Technical Consultant, are posted three business days in advance of the scheduled call. |
| **July** | **January** | The **IMS Clinical Data Consultant sends Action Items** requiring investigation or response to the Program Consultant and the Grantee within 5 business days after a data call. The CDC Program Consultant communicates a summary of the data review in a letter to the Grantee. |
| **August** | **February** | The **Grantee investigates Action Items** and completes responses in Sections I and II of the Submission Narrative and submits to IMS with the next CCDE submission.  |

**Software Selection:** Each grantee needs to identify computer software to use for data management. The decision must balance the unique needs of the program, the cost of developing an in-house system, as well as the suitability of available software. CDC provides an optional use database management system called Cancer Screening and Tracking (CaST) System, developed to track clients screened for cancer and to generate the data items required for CCDE reporting. Other options include developing a custom in-house system, adding to an existing health system in your Program, or purchasing software from vendors that have developed other CRCCP systems.

If at any time a grantee chooses to convert their existing data system to a different software package, please notify your CDC Program Consultant and IMS Clinical Data Consultant of your plans and timeline. It is also strongly recommended that a test data submission be sent to IMS for review once the conversion process is completed and validated. Grantees should wait for feedback on the test data submission prior to implementation of the new data system. The test submission should be done well in advance of a CCDE submission due date. The IMS Clinical Data Consultant should be notified prior to sending the test data file.

Similarly, it is strongly recommended that revised data collection forms should be sent to CDC and IMS for data management and clinical review before your program finalizes and implements the forms.

**CHAPTER 2**

**Colorectal Cancer Clinical Data Elements (CCDEs****)**

**Introduction to the CCDE Chapter**

The purpose of this chapter is to provide the grantees with the information necessary to collect the CCDE data.

* **Understanding the CCDE data**This section of the chapter provides information regarding the structure of the CCDEs, the definition of a screening cycle, information about collecting and reporting Race and Hispanic Origin data, creating a unique client identification number, and details regarding data conventions used in reporting CCDE items.
* **CCDE Field Descriptions**This section provides a detailed description of each CCDE data item. This is the format that must be followed for the CCDE data submissions submitted to CDC.

Note: CDC distributed a draft of the CCDE data set to grantees on 10/30/2009. The final version of the CCDE data set to be used by grantees was subsequently distributed on 12/02/2009. The CCDE Field Descriptions in this User’s Manual reflect the final CCDE data set.

The [www.crccp.org](http://www.crccp.org) Web site contains documentation of the revisions made between the draft CCDE data set and the final version of the CCDE data set.

**Understanding the CCDE Data**

**Colorectal Cancer Clinical Data Elements**

The Colorectal Cancer Clinical Data Elements (CCDEs) are a set of standardized data elements developed to ensure that consistent and complete information on client demographic characteristics, screening history, risk factors, screening and diagnostic tests, diagnosis, staging and treatment are collected on clients screened or diagnosed with program funds. These are the data items that are necessary for the grantees and the CDC to manage and evaluate the clinical component of the Colorectal Cancer Control Program. Grantees may collect additional data for local use (not to be reported to the CDC) if they choose. The CCDEs are collected for each screening event for each client, then computerized, converted into a standardized format, and transmitted to IMS.

**CCDE Cycle Definition**

A CCDE cycle is reported in one CCDE record. For clients that adhere to testing, a CCDE cycle begins with an initial colorectal cancer screening test and continues through any additional tests or procedures required for diagnostic evaluation following an abnormal or incomplete test, and ends when a final diagnosis is determined and treatment is initiated, if indicated.

**Tracking Screening Adherence**

Non-adherent clients that did not participate in screening are also reported in the CCDEs to track screening adherence across the program, which is a high priority for CDC. Non-adherent clients are those who initiated testing by receiving a fecal kit or appointment for a procedure, but did not follow through with testing. Each grantee program develops a policy and procedure to determine the timeframe and criteria to administratively close out a record as non-adherent. Refer to Data Items 5.1 and 5.2.

**Structure of the CCDEs**

The CCDEs consist of twelve sections. Each section contains specific variables to provide the CDC with detailed information about the client’s screening cycle.

***Section 1: Client and Record Identification***

This section identifies your Program and contains client IDs (to uniquely identify and track clients) and record IDs (to identify one record among many for a unique client ID). It must be completed for each client and each CCDE record for that client.

***Section 2: Demographic Information***

This section contains demographic information about clients. The information collected in this section must be self-reported by the clients. This information must be completed for each client and each CCDE record for that client.

***Section 3: Screening History***

This section contains information regarding previous colorectal screening tests. The information collected in this section can be self-reported by the client, or can come from information documented in the client’s medical record. Medical record information is preferred if available. This information must be completed for each client and each CCDE record for that client.

***Section 4: Assessed Risk***

This section contains risk factor information, such as previous diagnoses of precancerous polyps or colorectal cancer. It also captures information about family history of colorectal cancer and current symptoms experienced by the client. The information collected in this section can be self-reported by the client, or can come from information documented in the client’s medical record. Medical record information is preferred if available. This information must be completed for each client and each CCDE record for that client.

***Section 5: Screening Adherence***

This section contains information on the client’s adherence to screening once initiated with an appointment made or a fecal kit provided. Information is collected about the initial test appointment date and whether or not the test was performed. It includes information about fecal kit distribution and return. This section must be completed for each client and each CCDE record for that client.

***Section 6: Screening and Diagnostic Tests Performed***

This section contains information about the types of screening or diagnostic tests received by a client within each screening cycle. This information must be completed for each CCDE record where Section 5 (Screening Adherence) indicates “Test Performed”.

***Section 7: Pathology from all Endoscopy Tests Performed***

This section contains data regarding histology of any polyps or lesions discovered during the screening cycle, along with number and size of any adenomatous polyps or lesions. This section must be completed anytime the client had a biopsy or polypectomy performed during one of the tests in Section 6.

***Section 8: Diagnosis Information for Surgeries Performed to Complete Diagnosis***

This section contains data regarding the date of surgery and histology from the surgical resection. This section should be completed anytime the client has “surgery recommended to complete the final diagnosis” after one of the tests in Section 6.

***Section 9: Final Diagnosis***

This section contains data regarding the final diagnosis for a screening cycle, any complications of endoscopy or DCBE experienced by the client, and the recommended test to begin the next cycle. This section should be completed for each CCDE record with at least one test performed (Section 6).

***Section 10: Treatment Information***

This section collects treatment information for clients with a final diagnosis of cancer.

***Section 11: Registry Information for Cancer/High Grade Dysplasia***

This section collects staging information obtained after linking with the central cancer registry for diagnoses of cancer and high grade dysplasia.

***Section 12: Record Information***

This section includes the CCDE version for data reported and an end of record mark.

**Race and Hispanic Origin**

Federal Programs are required to use standards defined by the U.S. Office of Management and Budget (OMB) for the classification of race and ethnicity data. Additional information is available on the OMB Web site at <http://www.whitehouse.gov/omb>.

The race codes collected in the CCDEs model those required by the OMB. However, grantees may expand these categories during data collection to include racial subgroups that are represented in the local population if they choose. For example, a grantee may be established in an ethnic neighborhood where the clients may not feel that the CCDE category of ‘White’ is appropriate. In this instance, expanding the category to include ‘Egyptian' or ‘Israeli’ may promote a more complete collection of race information. In these instances, the data system would then collapse these categories into ‘White’ prior to the CCDE submission to the CDC.

The same would hold true for the collection of Hispanic or Latino origin. If a grantee finds that the Race fields are frequently left blank when Hispanic or Latino origin is reported as “Yes”, then it may be more advantageous to expand the Race categories to include ‘White – Hispanic’, ‘White – Non-Hispanic’, etc. These categories could then be expanded to report Hispanic Origin and Race prior to the CCDE submission to the CDC.

An expanded list of the CDC Race and Ethnicity Code Set is included in [Appendix B](#AppendixB) to assist grantees in collapsing more specific race concepts into the standard race code set.

**Unique Client Identifier**

The client identification number used in the CCDEs must be unique and consistent throughout the entire data system. It is important, for program purposes, to be able to track clients over time. A client identification number which is unique only to a clinic is not acceptable because it cannot track a client between clinics. Grantees may not have the capability to assign the same unique identifier to a client who changes clinics. In these programs, matching is routinely done to identify the relatively small number of clients who change clinics. Matching can be done using date of birth, name (first, last, and maiden), and Social Security Number. Using a combination of these items assures a greater number of accurate matches.

Completely numeric identifiers are preferred; however, the CCDEs allow the use of alpha-numeric client identifiers, if necessary. Confidentiality is of the utmost importance. The CDC does not want an identification number that could be used to link the CCDEs to other databases. While a Social Security Number could be used, you must encode it prior to submission to the CDC. See the item description on Client ID for encoding procedures.

**Data Conventions**

These are the general data conventions that apply to the CCDE data. However, the specific information on each field should be followed for a CCDE submission.

**Dates****:** All dates are entered in the form MMDDYYYY. For example, January 6, 1942 should be reported as 01061942. If any part of the date is unknown, blank fill just that part. For example, if the month and year are known, but the day is not, blank fill just the day

(e.g., 01 1942). Date fields may not be missing the year value.

**Alphanumeric Fields**: Alphanumeric or character data must be left-justified. In a left-justified field, the field value is placed so that the first character of the value is in the first position of the field. For example, Item 1.2 (Client Identifier) is left-justified in the CCDE file. The starting and ending positions are columns 4 through 18. If the Client Identifier is 1234, then “1234“ should be placed in columns 4 through 7 and columns 8 through 18 would be filled with blanks as shown here: “1234 “.

**Numeric Fields****:** Numeric fields are right-justified. In a right-justified field, the field value is placed so that the last character of the value is in the last position of the field. For example, Item 1.3 (Record Identifier) is a 6-digit numeric code and it is right justified. The starting and ending positions are 19 through 24. If the record identifier is 1, then “1” should be placed in column 24 and columns 19 through 23 should be blank, as shown here: “ 1”. Numeric fields may also be reported using leading zeroes, as shown here: “000001”. Grantees are asked to be consistent in how numeric values are placed.

**Blank Filled Fields****:** A blank filled field is filled with blank characters. If the field has a length of six and it is appropriate to blank fill the field, then it should contain six blank characters. It is only appropriate to blank fill a field when it is indicated in the item description. A blank field should not be used as a substitute for an "unknown" response if a valid "unknown" code exists.

**CCDE Field Descriptions**

ITEM NO / NAME: **1.1: Program**

PURPOSE: To indicate the unique identifier for the grantee program.

LENGTH: 3

FIELD LOCATION: 1-3

TYPE: Numeric – right justify. Include leading zeroes.

SKIP PATTERN: This field should always be completed.

CONTENTS: 001 = Alabama (AL)

004 = Arizona (AZ)

006 = California (CA)

008 = Colorado (CO)

009 = Connecticut (CT)

010 = Delaware (DE)

012 = Florida (FL)

019 = Iowa (IA)

023 = Maine (ME)

024 = Maryland (MD)

025 = Massachusetts (MA)

027 = Minnesota (MN)

030 = Montana (MT)

031 = Nebraska (NE)

033 = New Hampshire (NH)

035 = New Mexico (NM)

036 = New York (NY)

041 = Oregon (OR)

042 = Pennsylvania (PA)

046 = South Dakota (SD)

049 = Utah (UT)

053 = Washington (WA)

Tribal Program Codes

090 = Arctic Slope (AC)

092 = Southcentral Foundation (SO)

098 = South Puget Intertribal Planning Agency (SP)

099 = Alaska Native Tribal Health Consortium (AN)

EXPLANATION: The state FIPS codes are the Federal Information Processing Standard codes developed by the National Bureau of Standards. The tribal program codes are codes assigned by the CDC to be used by the tribal programs in lieu of state FIPS codes.

EXAMPLE: For Arizona: 004

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **1.2: Client identifier**

PURPOSE: To indicate a system-generated identification number for each client that will be consistent for the client throughout the database.

LENGTH: 15

FIELD LOCATION: 4-18

TYPE: Alphanumeric (no special symbols) – left justify, case sensitive.

SKIP PATTERN: This field should always be completed.

CONTENTS: A fifteen-digit alphanumeric code. The client identifier must be unique and constant for each client in your database in order to track each client over time. A client identifier that is unique only to a specific clinic or location is not acceptable because it cannot track the client between locations. Completely numeric client identifiers are preferred; however, the CCDEs allow the use of alphanumeric client identifiers if you find it necessary. If alphabetic characters are included in the Client identifier field, they must be entered consistently in uppercase or lowercase for all records for each client.

 Confidentiality is of the utmost importance. The CDC does not want a client identifier that could be used to link CCDE records to other databases. Certain identification numbers such as Social Security Numbers lack this privacy. If Social Security Numbers are used, or any other number which has linking capabilities, then the client identifier must be encoded. The CDC does not want to know the encoding scheme used by your program. However, your program should derive an encoding scheme which you can decode to the original client identifier in the event that a problem is found. The use of partial names and/or dates is also not recommended.

 We provide the following suggestions and an example encoding procedure which we hope you will find helpful. Digit rotation and nines-complement are two methods which, when combined, can be used as an effective encoding scheme. Digit rotation is simply rotating a set of digits either left or right. The nines-complement of a number is nine minus the number, i.e. the nines-complement of 2 is 7, the nines-complement of 5 is 4 and the nines-complement of 0 is 9. An example of an encoding procedure for the Social Security Number, 123-45-6789 is as follows:

|  |  |
| --- | --- |
| **Procedure** | **Before/After** |
|  Nines-complement of digits 2,4,8,9 | 1**2**3-**4**5-67**89 /** 1**7**3-**5**5-67**10** |
| Rotate left - digits 1,3,5,6  | **1**7**3**-5**5**-**6**710 / **3**7**5**-5**6**-**1**710 |
| Rotate right - digits 2,3,8,9 | 3**75**-56-17**10 /** 3**07**-66-17**51** |

EXAMPLE: Client identifier is 001000002357901: 001000002357901

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **1.3: Record identifier**

PURPOSE: To identify one record among many for a client.

LENGTH: 6

FIELD LOCATION: 19-24

TYPE: Numeric – right justify

SKIP PATTERN: This field should always be completed.

CONTENTS: A six-digit numeric code. This field will be used to identify one unique record among many for a client. For example, the record identifier can be a visit date or a sequential record number.

EXPLANATION: A screening cycle begins with either an initial colorectal cancer test or the distribution of a fecal kit, continues through any additional tests required for diagnostic evaluation following an abnormal or incomplete test, and ends when a final diagnosis is reached and treatment is initiated, when required.

Each CCDE record identifies a unique screening cycle for a client. A client can have multiple screening cycles reported in the CCDE file. The record identifier helps to differentiate one screening cycle among many for a client. The record identifier could be the date of cycle initiation (e.g. FOBT date), or it could simply be a sequential number (e.g. 1 = first cycle, 2 = second cycle, etc).

Grantees are asked to be consistent in the method used for creating a record identifier.

EXAMPLE: Using a date of 4/1/2010: 040110

Using a cycle number of 1: 000001 or 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **2.1: Date of birth**

PURPOSE: To specify the date of birth self-reported by a client.

LENGTH: 8

FIELD LOCATION: 25-32

TYPE: Date

SKIP PATTERN: This field should always be completed.

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is the month of birth from 01 to 12, DD is the day of birth from 01 to 31, and YYYY is the year of birth, including the century. If just the year is known, then blank fill the month and day. If just the year and month are known, then blank fill the day (e.g. 01 1955). At a minimum, the year of birth must be reported.

EXPLANATION: Date of birth must be self-reported by the client. This field is used to compute age values and is vital to various analyses. It is, therefore, important to provide as complete a date as possible.

EXAMPLE: For a client born on May 1, 1953: 05011953

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **2.2: Gender**

PURPOSE: To specify the gender self-reported reported by a client.

LENGTH: 1

FIELD LOCATION: 33

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 1 = Male

 2 = Female

 9 = Other/unknown

EXPLANATION: Gender must be self-reported by the client. A response of 9 (Other/unknown) in the context of this question could mean that the client was not asked, the client’s answer was not recorded, the client self-identified with a gender other than male or female, or the client refused to answer the question.

EXAMPLE: Client is female: 2

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **2.3 Hispanic or Latino origin**

PURPOSE: To indicate the self-reported Hispanic or Latino Origin of a client.

LENGTH: 1

FIELD LOCATION: 34

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 1 = Yes

 2 = No

 9 = Unknown/missing

EXPLANATION: The method of identifying Hispanic or Latino Origin must be self-identification by the client. Consider placing this field prior to race on the data form for better completion of the race/ethnicity data.

 Hispanic Origin or Latino should be collected as a separate data field from race. If Hispanic or Latino Origin is not collected separately from race on your forms and a client reports race as Hispanic, then Item 2.3 (Hispanic or Latino origin) should be reported as 1 (Yes) and Item 2.4.1 (Race 1) should be reported as 9 (Unknown). If Hispanic or Latino Origin is not collected separately and a client reports race as something other than “Hispanic” or “Latino”, then Item 2.3 (Hispanic or Latino Origin) should be reported as 9 (Unknown/missing). If Hispanic or Latino Origin is not asked of the client, the answer is not recorded, the client doesn’t know or the client refuses to answer, then report 9 (Unknown/missing).

EXAMPLE: For a self-reported Hispanic or Latino client: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **2.4.1: Race 1**

PURPOSE: To indicate the first race that is self-reported by a client.

LENGTH: 1

FIELD LOCATION: 35

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 1 = White

2 = Black or African American

3 = Asian

4 = Native Hawaiian or Other Pacific Islander

5 = American Indian or Alaska Native

 9 = Unknown

EXPLANATION: The method of identifying race must be self-identification by the client. If a client reports more than one race category, then this field should be populated first; and Item 2.4.2 “Race 2” through Item 2.4.5 “Race 5” should be used sequentially, as needed, to report additional race categories. No primary race is collected. The Race 1 field has no significance over Race 2-5, and may simply be the first race that is mentioned or recorded by the client.

 If Item 2.3 (Hispanic or Latino origin) is not collected separately from race, and race is reported as “Hispanic”, then race should be reported to the CDC as 9 (Unknown) and Item 2.3 (Hispanic or Latino Origin) should be reported to the CDC as 1 (Yes).

The response options for this item are defined by the Office of Management and Budget (OMB) for the collection of race and ethnicity data. Additional information is available on the OMB Web site at <http://www.whitehouse.gov/omb/fedreg/1997standards.html>.

 A Race and Ethnicity Code Set is provided at the end of this chapter (Chapter 2) in [Appendix B](#AppendixB). The code set offers a detailed list of race concepts that can be used for data collection, and guidance for collapsing those detailed concepts into the standard form used in the CCDEs.

EXAMPLE: If a client self-identifies as Asian: 3

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **2.4.2: Race 2**

PURPOSE: To indicate the second race that is self-reported by a client.

LENGTH: 1

FIELD LOCATION: 36

TYPE: Numeric

SKIP PATTERN: This field should be completed when more than one race is self-reported by a client; otherwise, leave blank.

CONTENTS: 1 = White

2 = Black or African American

3 = Asian

4 = Native Hawaiian or Other Pacific Islander

5 = American Indian or Alaska Native

EXPLANATION: The method of identifying race must be self-identification by the client. This field should be left blank unless a client reports more than one race. No primary race is collected. The Race 1 field has no significance over Race 2, and Race 2 has no significance over the Race 3-5 fields. It may simply be the second race mentioned by a client. Unknown race must be reported in the Race 1 field.

The response options for this item are defined by the Office of Management and Budget (OMB) for the collection of race and ethnicity data. Additional information is available on the OMB Web site at <http://www.whitehouse.gov/omb/fedreg/1997standards.html>.

 A Race and Ethnicity Code Set is provided at the end of this chapter in [Appendix B](#AppendixB). The code set offers a detailed list of race concepts that can be used for data collection, and guidance for collapsing those detailed concepts into the standard form used in the CCDEs.

EXAMPLE: If a client identifies as Asian and White: Race 1 = 3 and Race 2 = 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **2.4.3: Race 3**

PURPOSE: To indicate the third race that is self-reported by a client.

LENGTH: 1

FIELD LOCATION: 37

TYPE: Numeric

SKIP PATTERN: This field should be completed when more than two races are self-reported by a client; otherwise, leave blank.

CONTENTS: 1 = White

2 = Black or African American

3 = Asian

4 = Native Hawaiian or Other Pacific Islander

5 = American Indian or Alaska Native

EXPLANATION: The method of identifying race must be self-identification by the client. This field should be left blank unless a client reports more than two races. No primary race is collected. The Race 1-2 fields have no significance over the Race 3-5 fields. It may simply be the third race mentioned by a client. Unknown race must be reported in the Race 1 field.

The response options for this item are defined by the Office of Management and Budget (OMB) for the collection of race and ethnicity data. Additional information is available on the OMB Web site at <http://www.whitehouse.gov/omb/fedreg/1997standards.html>.

 A Race and Ethnicity Code Set is provided at the end of this chapter in [Appendix B](#AppendixB). The code set offers a detailed list of race concepts that can be used for data collection, and guidance for collapsing those detailed concepts into the standard form used in the CCDEs.

EXAMPLE: If a client identifies as Asian, White and African American: Race 1 = 3; Race 2 = 1; and Race 3 = 2

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **2.4.4: Race 4**

PURPOSE: To indicate the fourth race that is self-reported by a client.

LENGTH: 1

FIELD LOCATION: 38

TYPE: Numeric

SKIP PATTERN: This field should be completed when more than three races are self-reported by a client; otherwise, leave blank.

CONTENTS: 1 = White

2 = Black or African American

3 = Asian

4 = Native Hawaiian or Other Pacific Islander

5 = American Indian or Alaska Native

EXPLANATION: The method of identifying race must be self-identification by the client. This field should be left blank unless a client reports more than three races. No primary race is collected. The Race 1-3 fields have no significance over the Race 4-5 fields. It may simply be the fourth race mentioned by a client. Unknown race must be reported in the Race 1 field.

The response options for this item are defined by the Office of Management and Budget (OMB) for the collection of race and ethnicity data. Additional information is available on the OMB Web site at <http://www.whitehouse.gov/omb/fedreg/1997standards.html>.

 A Race and Ethnicity Code Set is provided at the end of this chapter in [Appendix B](#AppendixB). The code set offers a detailed list of race concepts that can be used for data collection, and guidance for collapsing those detailed concepts into the standard form used in the CCDEs.

EXAMPLE: If a client identifies as Asian, White, African American and Alaska Native: Race 1 = 3; Race 2 = 1; Race 3 = 2; and Race 4 = 5

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **2.4.5: Race 5**

PURPOSE: To indicate the fifth race that is self-reported by a client.

LENGTH: 1

FIELD LOCATION: 39

TYPE: Numeric

SKIP PATTERN: This field should be completed when more than four races are self-reported by a client; otherwise, leave blank.

CONTENTS: 1 = White

2 = Black or African American

3 = Asian

4 = Native Hawaiian or Other Pacific Islander

5 = American Indian or Alaska Native

EXPLANATION: The method of identifying race must be self-identification by the client. This field should be left blank unless a client reports more than four races. No primary race is collected. The Race 1-4 fields have no significance over the Race 5 field. It may simply be the fifth race mentioned by a client. No more than five races will be reported for a client in any CCDE record. Unknown race must be reported in the Race 1 field.

The response options for this item are defined by the Office of Management and Budget (OMB) for the collection of race and ethnicity data. Additional information is available on the OMB Web site at <http://www.whitehouse.gov/omb/fedreg/1997standards.html>.

 A Race and Ethnicity Code Set is provided at the end of this chapter in [Appendix B](#AppendixB). The code set offers a detailed list of race concepts that can be used for data collection, and guidance for collapsing those detailed concepts into the standard form used in the CCDEs.

EXAMPLE: If a client identifies as Asian, White, African American, Alaskan Native and Hawaiian: Race 1 = 3; Race 2 = 1; Race 3 = 2; Race 4 = 5; and Race 5 = 4

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **2.5: State of residence**

PURPOSE: To indicate the FIPS code for a client’s state of residence.

LENGTH: 2

FIELD LOCATION: 40-41

TYPE: Numeric - right justify

SKIP PATTERN: If known, this field should be completed; otherwise, leave blank.

CONTENTS: A 2-digit numeric code.

EXPLANATION: State of residence must be self-reported by the client. The state Federal Information Processing Standard (FIPS) codes are developed by the National Institute of Standards and Technology (NIST) and are available at

<http://www.itl.nist.gov/fipspubs/fip5-2.htm>. There is a code for each state and territory.

EXAMPLE: Client’s state of residence is Maryland: 24

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **2.6 County of residence**

PURPOSE: To indicate the FIPS code for a client’s county of residence.

LENGTH: 3

FIELD LOCATION: 42-44

TYPE: Numeric - right justify

SKIP PATTERN: If known, this field should be completed; otherwise, leave blank.

CONTENTS: A 3-digit numeric code relevant to the State of residence reported in Item 2.5.

EXPLANATION: County of residence must be self-reported by the client. The county FIPS codes are the Federal Information Processing Standard codes developed by the National Institute of Standards and Technology (NIST) and are available at <http://www.itl.nist.gov/fipspubs/co-codes/states.htm>. There is a 3-digit code for each county in a state or territory. If the state or territory where the client lives does not have counties, enter 999.

EXAMPLE: Client’s county of residence is Frontier, Nebraska: 063

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **3.1: Has client ever had a colorectal screening test?**

PURPOSE: To indicate if a client has previously received any of the following colorectal screening tests: take-home FOBT, take-home FIT, sigmoidoscopy, colonoscopy, DCBE, CTC (virtual colonoscopy) or stool DNA.

LENGTH: 1

FIELD LOCATION: 45

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 1 = Yes

 2 = No

 9 = Unknown

EXPLANATION: This information can be self-reported by the client, or can come from information documented in the client’s medical record. Medical record information is preferred, if available. Fecal tests done by a provider in an office are not acceptable and should not be recorded in this field.

If the client has had any of the above noted colorectal screening tests in the past, then complete this field as 1 (Yes). If the client has never had a colorectal screening test prior to the visit, then complete this field as 2 (No). If the client has had a previous colorectal screening test within the program (as part of a separate screening cycle), complete this field as 1 (Yes).

 A response of 9 (Unknown) in the context of this question may mean that the client was not asked, the answer was not recorded, the client was unsure, or the client refused to answer the question.

EXAMPLE: If a client has previously had a take-home FOBT or FIT: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **4.1: Personal history of CRC (colorectal cancer) or precancerous polyps**

PURPOSE: To indicate if a client has ever been diagnosed with colorectal cancer or adenomatous/pre-cancerous polyps.

LENGTH: 1

FIELD LOCATION: 46

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

If Item 4.1 (Personal history of CRC (colorectal cancer) or precancerous polyps) = 1 (Yes), then Item 6.0 (Indication for test 1) should not = 1 (Screening).

CONTENTS: 1 = Yes

 2 = No

 9 = Unknown

EXPLANATION: This field is used to indicate if a client has ever been diagnosed with colorectal cancer, which is cancer of the colon or rectum. Other possible terms for CRC include colon cancer, rectal cancer, cancer of the large intestine, cancer of the large bowel, and bowel cancer. Anal cancer, or cancer of the anus, should not be reported in this field.

It should also be used to indicate if the client has ever been diagnosed with a precancerous polyp or pre-malignant polyp. A precancerous/pre-malignant polyp would include any adenomatous polyps. A response of 1 (Yes) will indicate that the client is at increased risk for CRC, and Item 6.0 (Indication for test 1) cannot be reported as 1 (Screening).

 This information can be self-reported by the client, or can come from information documented in the client’s medical record. Medical record information is preferred, if available. If the client indicates that he/she has been previously diagnosed with CRC or had a precancerous polyp, then this field should be completed as 1 (Yes). If the client has never been diagnosed with CRC or a pre-cancerous polyp prior to the visit, then complete this field as 2 (No).

 A response of 9 (Unknown) in the context of this question may mean that the client was not asked, the answer was not recorded, the client was unsure, or the client refused to answer the question.

EXAMPLE: A client indicates he/she was diagnosed with CRC previously: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **4.2: Family history of CRC**

PURPOSE: To indicate if the client has a family history of colorectal cancer.

LENGTH: 1

FIELD LOCATION: 47

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 1 = Yes

 2 = No

 9 = Unknown

EXPLANATION: This information should be self-reported by the client, or can come from information documented in the client’s medical record. Medical record information is preferred, if available.

 The information reported in this field may include ***family history of either CRC or adenomatous polyps.***

 Each grantee, in conjunction with the Medical Advisory Board, will determine criteria and type of screening test offered for clients at increased risk for CRC due to family history of CRC or adenomatous polyps. These criteria should be consistent with available guidelines.

EXAMPLE: A client’s father was diagnosed with CRC: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **4.3: Currently experiencing CRC symptoms**

PURPOSE: To indicate if the client is currently experiencing colorectal cancer symptoms.

LENGTH: 1

FIELD LOCATION: 48

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 1 = Yes

 2 = No

 9 = Unknown

EXPLANATION: This information can be self-reported by the client, or can come from information documented in the client’s medical record. Medical record information is preferred, if available.

Each grantee should work with its Medical Advisory Board to define a list of symptoms requiring medical evaluation. The list may include, but may not be 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.

If the response is 1 (Yes), then the client is clinically ineligible for CRCCP funded testing, and will need to be referred out of the program for the appropriate medical care or evaluation.

If a clinically ineligible client is subsequently evaluated and cleared for screening, they may be enrolled for CRCCP funded testing with Item 4.3 updated from 1 (Yes) to 2 (No).

EXAMPLE: The client is not currently experiencing any CRC symptoms: 2

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **5.1: Initial test appointment date, or date fecal kit distributed**

PURPOSE: To indicate the date testing was initiated for a client based on date of FOBT/FIT kit distribution or the initial appointment date for the first test recommended within this cycle.

LENGTH: 8

FIELD LOCATION: 49 - 56

TYPE: Date

SKIP PATTERN: This field should always be completed.

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is a value from 01 to 12, DD is a value from 01 to 31, and YYYY is the year, including the century. No part of this date field may be left blank.

If a month or day is unknown, then that part of the date should be completed using a valid default value. Each grantee should decide upon the default values to be used for unknown month and/or day, and should apply them consistently. For example, your Program may choose to use “06” for unknown month and “15” for unknown day. Do not use “99” to report unknown month or day values.

EXPLANATION: If the initial test was a take-home FOBT or take-home FIT, then indicate the date that the fecal kit was distributed to the client. Otherwise, indicate the initial appointment date scheduled for the first test.

EXAMPLE: If an FOBT kit was mailed to the client on 3/5/2010: 03052010

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **5.2: Screening adherence**

PURPOSE: To indicate if the client received the initial test recommended.

LENGTH: 1

FIELD LOCATION: 57

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

If Item 5.2 (Screening adherence) = 1 (Test Performed), then Section 6 must be completed to report at least one test performed.

If Item 5.2 (Screening adherence) is not = 1 (Test Performed), then Sections 6 through 11 should be left blank. Section 12 must be completed for each record.

CONTENTS: 1 = Test Performed

 2 = Test Pending

 3 = No test performed, FOBT/FIT card not returned

 4 = No test performed, appointment not kept

EXPLANATION: Each grantee will need to establish guidelines to determine when a fecal kit is considered unreturned, how much time can elapse or the number of appointments rescheduled before a client is considered an appointment no show.

If the client returns the fecal kit, or receives the initial test within the timeline established by the grantee, indicate 1 (Test performed).

If at the time of CCDE data submission, the client has not returned the fecal kit or received an initial test, but the timeframe established has not expired, indicate 2 (Test pending).

If the established timeframe has been reached, and the fecal kit has not been returned, indicate 3 (No test performed, FOBT/FIT card not returned). The CCDE cycle should be considered closed. In the event that an alternative test, such as a colonoscopy, is provided to the client, the colonoscopy should be recorded in a new CCDE cycle as the initial test.

If, once the established timeframe has been reached, and the appointment for the initial test has not been kept, indicate 4 (No test performed, appointment not kept). The CCDE cycle should be considered closed. This does not mean that attempts to get the client in for testing should stop. If the client does return for an initial test, a new CCDE cycle should be created.

EXAMPLE: If the client returns their FOBT kit: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.0: Indication for test 1**

PURPOSE: To report the indication or purpose for the first test provided to the client, reported in Item 6.1.01 (Test 1 performed).

LENGTH: 1

FIELD LOCATION: 58

TYPE: Numeric

SKIP PATTERN: This field should be completed when 5.2 (Screening Adherence = 1 (Test Performed).

If Item 4.1 (Personal history of CRC (colorectal cancer) or precancerous polyps) = 1 (Yes), then Item 6.0 (Indication for test 1) should not = 1 (Screening).

CONTENTS: 1 = Screening
2 = Surveillance
3 = Diagnostic
9 = Unknown

EXPLANATION: A screening test (1) is a test provided for a client who has no colorectal cancer symptoms, may have never been screened for colorectal cancer, or may have had a previous screening test without significant findings and is due for routine rescreening.

A surveillance test (2) is a test (typically a colonoscopy) done at more frequent intervals than screening to evaluate a client who has a known history of colorectal polyps or colorectal cancer, to look for recurrence of these. The appropriate intervals for surveillance tests can be found in published guidelines.

A diagnostic test (3) is a test (typically a DCBE or colonoscopy) performed to evaluate signs or symptoms or to follow-up an abnormal screening test. An indication of 3 (Diagnostic) should occur infrequently, and should be monitored by grantees.

If the first test to be provided is a take-home fecal kit (FOBT or FIT), then the Indication for test 1 should not = 3 (Diagnostic). If the first test to be provided is a DCBE, then the Indication for test 1 should not = 1 (Screening).

EXAMPLE: If the purpose of the first test provided is for screening: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.1.01:** **Test 1 performed**

PURPOSE: To indicate the first test received by the client within the current cycle.

LENGTH: 1

FIELD LOCATION: 59

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 5.2 (Screening Adherence) = 1 (Test Performed).

If Item 6.0 (Indication for test 1) = 1 (Screening), then Item 6.1.01 should not = 5 (DCBE).

If Item 6.0 (Indication for test 1) = 3 (Diagnostic), then Item 6.1.01 should only = 4 or 5.

CONTENTS: 1 = Take-home Fecal Occult Blood Test (FOBT)
2 = Take-home Fecal Immunochemical Test (FIT)
3 = Sigmoidoscopy
4 = Colonoscopy
5 = Double-contrast Barium Enema (DCBE)
7 = Other

EXPLANATION: This field should be reported with the first test received by the client within the current cycle.

EXAMPLE: If the first test provided to the client is a sigmoidoscopy: 3

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.1.02:** **Test 1 performed – Other specify**

PURPOSE: To specify the type of “other” test indicated in Item 6.1.01 (Test 1 performed).

LENGTH: 40

FIELD LOCATION: 60 - 99

TYPE: Free text

SKIP PATTERN: This field should be completed when Item 6.1.01 (Test 1 performed) = 7 (Other); otherwise, leave blank.

EXPLANATION: This field captures the type of “other” test indicated in Item 6.1.01. Use this item appropriately. Reclaiming inappropriate “other” responses is time consuming and could potentially result in the loss of valuable data.

EXAMPLE: If a virtual colonoscopy is performed: virtual colonoscopy

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.1.03:** **Date of test 1**

PURPOSE: To specify the date of the first test.

LENGTH: 8

FIELD LOCATION: 100 - 107

TYPE: Date

SKIP PATTERN: This field should be completed when Item 5.2 (Screening Adherence) = 1 (Test Performed).

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is the month from 01 to 12, DD is the day from 01 to 31, and YYYY is the year of the test, including the century. If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 08 2010). This field should not be left completely blank if a first test was performed.

EXPLANATION: This field captures the date that test 1 is performed. If the test is a take-home FOBT or FIT, then report the date that the kit was processed.

If a test was recommended, but the appointment was not kept, or the FOBT/FIT kit was not returned, then this information should be reported in Item 5.1 (Initial test appointment date, or date fecal kit distributed) and Item 5.2 (Screening adherence). Items in Section 6 (Screening and Diagnostic Tests Performed) are limited to reporting data on tests that were completed.

EXAMPLE: If a colonoscopy is performed on August 1, 2010: 08012010

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.1.04:** **Provider specialty**

PURPOSE: To report the specialty of the clinician providing the first test.

LENGTH: 2

FIELD LOCATION: 108 - 109

TYPE: Numeric - right justify

SKIP PATTERN: This field should be completed when Item 5.2 (Screening Adherence) = 1 (Test Performed).

CONTENTS: 1 = General practitioner
 2 = Internist
 3 = Family practitioner
 4 = Gastroenterologist
 5 = General surgeon
 6 = Colorectal surgeon
 7 = Licensed practical nurse
 8 = Registered nurse
 9 = Nurse practitioner
10 = Physician assistant
11 = Administrator, if FOBT/FIT mailed by non-clinician
12 = Radiologist
13 = Obstetrician/Gynecologist (OB/GYN)
99 = Unknown

EXPLANATION: This field should capture the medical practice specialty of the provider who performed or provided the first test reported in Item 6.1.01.

If the first test is an FOBT/FIT, capture the specialty of the individual that made the assessment that a FOBT/FIT should be provided to the client.

A response of 11 (Administrator, if FOBT/FIT mailed by non-clinician) should be used only when an administrator, not a clinician, makes the assessment that a FOBT/FIT kit should be provided to the client.

EXAMPLE: If the provider specialty for the first test is a general surgeon: 5

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.1.05:** **Result of test 1**

PURPOSE: To specify the result of test 1.

LENGTH: 1

FIELD LOCATION: 110

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 5.2 (Screening Adherence) = 1 (Test Performed).

 If Item 6.1.01 (Test 1 performed) = 1 (Take-home FOBT) or 2 (Take-home FIT), then Item 6.1.05 must = 5, 6, 7 or 9.

If Item 6.1.01 (Test 1 performed) = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE), then Item 6.1.05 must = 1- 4, 7 or 9.

If Item 6.1.01 (Test 1 performed) = 7 (Other), then Item 6.1.05 must be reported using the result that is appropriate for the test performed and specified in Item 6.1.02 (Test 1 performed – other specify).

CONTENTS: 1 = Normal/Negative/Diverticulosis/Hemorrhoids
2 = Other finding not suggestive of cancer or polyp(s)
3 = Polyp(s), or Lesion(s) suspicious for cancer
4 = Inadequate/Incomplete test with no findings
5 = FOBT/FIT/Other Test Performed Negative
6 = FOBT/FIT/Other Test Performed Positive
7 = Pending
9 = Unknown

EXPLANATION: If more than one result is noted on the medical chart, then report the most severe.

For take-home FOBT, take-home FIT or other similar stool tests, if the medical chart records any gradation of positive (e.g. “weakly positive” or “slightly positive”), then Item 6.1.05 should be recorded as 6 (FOBT/FIT/Other Test Performed Positive).

A response of 2 (Other finding not suggestive of cancer or polyp(s) should be used when the endoscopy report indicates a specific finding, but the finding is not a cancerous lesion or a polyp. Examples of Other findings may include:

* Colitis (inflammation of the bowel wall)
* Arteriovenous malformation
* Ulcerative colitis
* Crohn’s colitis

A result of 4 (Inadequate/Incomplete) should only be reported when the endoscopy report notes that an exam was started but was incomplete or inadequate, and does not report any specific findings. Incomplete or inadequate tests may occur due to client discomfort or distress, bowel obstruction, inadequate bowel preparation (the bowel was not adequately cleared of fecal material) or physician fatigue.

 If the endoscopy report notes specific findings, even during an incomplete or inadequate test, then the test result should reflect the observations and be reported using response options 1, 2 or 3.

 When a Test Result = 4 (Inadequate/Incomplete), then Item 6.1.09 (Test Outcome) should be coded as 2 (Incomplete/Inadequate) and an additional test should be recommended.

EXAMPLE: If result of the take-home FOBT is positive: 6

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.1.06:** **Was a biopsy/polypectomy performed during the endoscopy?**

PURPOSE: To indicate if a biopsy or polypectomy was performed during the sigmoidoscopy or colonoscopy.

LENGTH: 1

FIELD LOCATION: 111

TYPE: Numeric

SKIP PATTERN: If Item 6.1.06 = 1 (Yes), then Item 7.1 (Histology of most severe polyp/lesion) must be completed.

Leave blank if Item 6.1.01 (Test 1 performed) = 1 (Take-home FOBT), 2 (Take-home FIT), 5 (DCBE) or 7 (Other).

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: This field should only be completed if the first test provided is either a colonoscopy or sigmoidoscopy.

If a biopsy was performed (1), then Item 7.1 (Histology of most severe polyp/lesion) must be completed.

EXAMPLE: If a polypectomy was performed during a colonoscopy: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.1.07:** **Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE?**

PURPOSE: To indicate the adequacy of the bowel preparation for a sigmoidoscopy, colonoscopy or DCBE.

LENGTH: 1

FIELD LOCATION: 112

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.1.01 (Test 1 performed) = 3 (Sigmoidoscopy), 4 (Colonoscopy), 5 (DCBE) or 7 (Other); otherwise, leave blank.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: Adequacy of the bowel preparation will be determined by the clinician performing the test. A response of 1 (Yes) or 2 (No) can only be reported if the procedure report explicitly states that the bowel preparation was adequate or inadequate; otherwise report 9 (Unknown).

If Test 1 = 7 (Other) and the procedure does not require bowel preparation, please code the adequacy of bowel preparation as 9 (Unknown).

If the adequacy of bowel preparation = 2 (No), then Item 6.1.09 (Test outcome) should be coded as 2 (Incomplete/Inadequate).

 The standardized colonoscopy reporting and data system (CO-RADs) quality measure for adequacy of bowel prep is described as adequacy to detect polyps > 5 mm.

EXAMPLE: If procedure report indicates adequate bowel preparation: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.1.08:** **Was the cecum reached during the colonoscopy?**

PURPOSE: To indicate whether or not the procedure report notes that the cecum was reached during the colonoscopy.

LENGTH: 1

FIELD LOCATION: 113

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.1.01 (Test 1 performed) = 4 (Colonoscopy); otherwise, leave blank.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: The procedure report must explicitly state that the cecum was reached or not reached during the colonoscopy in order to report 1 (Yes) or 2 (No); otherwise, report 9 (Unknown).

If the 6.1.08 = 2 (No), then 6.1.09 (Outcome) should be coded as 2 (Incomplete/Inadequate).

EXAMPLE: If cecum was not reached: 2

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.01 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.1.09:** **Test 1 outcome**

PURPOSE: To indicate if the test reported in Item 6.1.01 was complete.

LENGTH: 1

FIELD LOCATION: 114

TYPE: Numeric

SKIP PATTERN: If Item 6.1.05 (Result of test 1) = 5 (FOBT/FIT/Other Test Performed Negative) or 6 (FOBT/FIT/Other Test Performed Positive), then Item 6.1.09 should = 1 (Complete).

If Item 6.1.05 (Result of test 1) = 4 (Inadequate/Incomplete test with no findings), then Item 6.1.09 should = 2 (Incomplete/Inadequate).

If Item 6.1.07 (Bowel Prep Adequacy) = 2 (No), then Item 6.1.09 should = 2 (Incomplete/Inadequate).

If Item 6.1.08 (Cecum reached) = 2 (No), then Item 6.1.09 should = 2 (Incomplete/Inadequate).

CONTENTS: 1 = Complete
2 = Incomplete/Inadequate

EXPLANATION: Each test provided should have a specific result that is reported in Item 6.1.05 (Result of test 1). If the test was completed satisfactorily, report 1 (Complete).

If there were circumstances that prevented the test from being performed satisfactorily such as an obstruction, inadequate bowel prep, or the cecum was not reached during colonoscopy, then report 2 (Incomplete/Inadequate).

If there are multiple polyps, and some of those polyps are extremely small (< 5mm), it is acceptable for the provider to choose not to remove the smaller polyps. In these instances, the Test Outcome would be considered 1 (Complete). If the recommendation of a repeat colonoscopy in 3-6 months is made, then that procedure would begin a new cycle where the indication (Item 6.0) would be reported as 2 (Surveillance).

If the provider recommends an immediate repeat exam (or additional tests needed to come to a Final Diagnosis) due to the incomplete, or non-removal of a significant polyp, then report 2 (Incomplete/Inadequate). Report the repeat exam (or additional tests needed) as Test 2.

EXAMPLE: If the colonoscopy is considered complete: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.1.10:** **Recommended next follow-up procedure within this cycle.**

PURPOSE: To indicate the next recommended procedure following the completion of Test 1 needed to complete this cycle. (This should not be confused with Item 9.04 to report the next test recommended for re-screening or surveillance.)

LENGTH: 1

FIELD LOCATION: 115

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 5.2 (Screening Adherence = 1 (Test Performed).

CONTENTS: 1 = Sigmoidoscopy
2 = Colonoscopy
3 = DCBE
4 = Surgery to complete diagnosis
7 = Other
8 = None (cycle is complete)

EXPLANATION: Once test 1 is completed, the next recommended procedure within the screening cycle should be reported. The next recommended test within the screening cycle should either be a diagnostic test to follow-up a positive initial screening test or another screening test where the first screening test was incomplete or inconclusive.

 If the next recommended follow-up procedure within the cycle is 4 (surgery to completed diagnosis) or 8 (none), then Items (6.2.01, 6.3.01 or 6.4.01, Tests2-4 performed) should be coded with 0 (None).

In the rare event that surgery is needed to complete diagnosis, Items 8.1 and 8.2 should then be completed, along with any final diagnosis and treatment data where applicable.

There may be rare instances in which it is appropriate for an FOBT or FIT to be recommended as a follow-up procedure within the cycle and reported as Test 2. In these instances Item 6.1.10 should be reported as 7 (Other). Item 6.1.11 (Other recommended test, specify) should be completed to indicate FOBT or FIT as the recommended next test within the cycle. These instances may include:

* The initial FOBT or FIT card could not be read by the lab
* Client did not perform the initial FOBT or FIT correctly
* An FOBT or FIT is recommended as follow-up to an incomplete or inconclusive colonoscopy that cannot be repeated

EXAMPLE: If a DCBE is recommended as the next procedure within this client’s “cycle”: 3

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.1.11:** **Other recommended test, specify**

PURPOSE: To specify the Other test recommended in Item 6.1.10.

LENGTH: 40

FIELD LOCATION: 116 - 155

TYPE: Free text.

SKIP PATTERN: This field should be completed when Item 6.1.10 (Recommended next follow-up procedure within this cycle) is reported as 7 (Other); otherwise, leave blank.

EXPLANATION: This field captures the type of “other” test indicated in Item 6.1.10. Use this item appropriately. Reclaiming inappropriate “other” responses is time consuming and could potentially result in the loss of valuable data.

EXAMPLE: If the next recommended test is a virtual colonoscopy: virtual colonoscopy

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.2.01:** **Test 2 performed**

PURPOSE: To indicate the second test received by the client within the current cycle.

LENGTH: 1

FIELD LOCATION: 156

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 5.2 (Screening Adherence) = 1 (Test Performed).

CONTENTS: 0 = None
3 = Sigmoidoscopy
4 = Colonoscopy
5 = Double-contrast Barium Enema (DCBE)
7 = Other

EXPLANATION: This field should be reported with the second test received by the client within the current cycle.

EXAMPLE: If the second test provided to the client is a DCBE: 5

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.2.02:** **Test 2 performed – Other specify**

PURPOSE: To specify the type of “other” test indicated in Item 6.2.01 (Test 2 performed).

LENGTH: 40

FIELD LOCATION: 157 - 196

TYPE: Free text

SKIP PATTERN: This field should be completed when Item 6.2.01 (Test 2 performed) = 7 (Other); otherwise, leave blank.

EXPLANATION: This field captures the type of “other” test indicated in Item 6.2.01. Use this item appropriately. Reclaiming inappropriate “other” responses is time consuming and could potentially result in the loss of valuable data.

EXAMPLE: If a virtual colonoscopy is performed: virtual colonoscopy

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.2.03:** **Date of Test 2**

PURPOSE: To specify the date of the second test.

LENGTH: 8

FIELD LOCATION: 197 - 204

TYPE: Date

SKIP PATTERN: This field should be completed when Item 6.2.01 (Test 2 performed) is not = 0 (None).

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is month from 01 to 12, DD is the day from 01 to 31, and YYYY is the year of the test, including the century. If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 08 2010). This field should not be left completely blank if a second test was performed.

EXPLANATION: This field captures the date that Test 2 is performed.

EXAMPLE: If a colonoscopy is performed on August 1, 2010: 08012010

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.2.04:** **Provider specialty**

PURPOSE: To report the specialty of the clinician providing the second test.

LENGTH: 2

FIELD LOCATION: 205 - 206

TYPE: Numeric - right justify

SKIP PATTERN: This field should be completed when Item 6.2.01 (Test 2 performed) is not = 0 (None).

CONTENTS: 1 = General practitioner
 2 = Internist
 3 = Family practitioner
 4 = Gastroenterologist
 5 = General surgeon
 6 = Colorectal surgeon
 7 = Licensed practical nurse
 8 = Registered nurse
 9 = Nurse practitioner
10 = Physician assistant
12 = Radiologist
13 = Obstetrician/Gynecologist (OB/GYN)
99 = Unknown

EXPLANATION: This field should capture the medical practice specialty of the provider who performed or provided the first test reported in Item 6.2.01.

EXAMPLE: If the provider specialty for the second test is a general surgeon: 5

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.2.05:** **Result of Test 2**

PURPOSE: To specify the results of Test 2.

LENGTH: 1

FIELD LOCATION: 207

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.2.01 (Test 2 performed) is not = 0 (None).

If Item 6.2.01 = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE), then Item 6.2.05 must = 1 - 4, 7 or 9.

If Item 6.2.01 = 7 (Other), then Item 6.2.05 must be reported using the result that is appropriate for the test performed and specified in Item 6.2.02

CONTENTS: 1 = Normal/Negative/Diverticulosis/Hemorrhoids
2 = Other finding not suggestive of cancer or polyp(s)
3 = Polyp(s), or Lesion(s) suspicious for cancer
4 = Inadequate/Incomplete test with no findings
5 = FOBT/FIT/Other Test Performed Negative
6 = FOBT/FIT/Other Test Performed Positive
7 = Pending
9 = Unknown

EXPLANATION: If more than one result is noted on the medical chart, then report the most severe.

A response of 2 (Other finding not suggestive of cancer or polyp(s) should be used when the endoscopy report indicates a specific finding, but the finding is not a cancerous lesion or a polyp.

A result of 4 (Inadequate/Incomplete) should only be reported when the endoscopy report notes that an exam was started but was incomplete or inadequate, and does not report any specific findings. Incomplete or inadequate tests may occur due to client discomfort or distress, bowel obstruction, inadequate bowel preparation (the bowel was not adequately cleared of fecal material) or physician fatigue.

 If the endoscopy report notes specific findings, even during an incomplete or inadequate test, then the test result should reflect the observations and be reported using response options 1, 2 or 3.

 When a Test Result = 4 (Inadequate/Incomplete), then Item 6.1.09 (Test Outcome) should be coded as 2 (Incomplete/Inadequate) and an additional test should be recommended.

EXAMPLE: If result of the colonoscopy is normal: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.2.06:** **Was a biopsy/polypectomy performed during the endoscopy?**

PURPOSE: To indicate if a biopsy or polypectomy was performed during the sigmoidoscopy or colonoscopy.

LENGTH: 1

FIELD LOCATION: 208

TYPE: Numeric

SKIP PATTERN: If Item 6.2.06 = 1 (Yes), then Item 7.1 (Histology of most severe polyp/lesion) must be completed.

Leave blank if Item 6.2.01 = 0, 5 or 7.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: This field should only be completed if the second test provided is either a colonoscopy or sigmoidoscopy.

If a biopsy was performed (1), then Item 7.1 (Histology of most severe polyp/lesion) must be completed.

EXAMPLE: If a polypectomy was performed during a colonoscopy: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.2.07:** **Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE?**

PURPOSE: To indicate the adequacy of the bowel preparation for a sigmoidoscopy, colonoscopy or DCBE.

LENGTH: 1

FIELD LOCATION: 209

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.2.01 (Test 2 performed) = 3 (Sigmoidoscopy), 4 (Colonoscopy), 5 (DCBE) or 7 (Other); otherwise, leave blank.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: Adequacy of the bowel preparation will be determined by the clinician performing the test. A response of 1 (Yes) or 2 (No) can only be reported if the procedure report explicitly states that the bowel preparation was adequate or inadequate; otherwise report 9 (Unknown).

If Test 2 = 7 (Other) and the procedure does not require bowel preparation, please code the adequacy of bowel preparation as 9 (Unknown).

If the adequacy of bowel preparation = 2 (No), then Item 6.2.09 (Test outcome) should be coded as 2 (Incomplete/Inadequate).

 The standardized colonoscopy reporting and data system (CO-RADs) quality measure for adequacy of bowel prep is described as adequacy to detect polyps > 5 mm.

EXAMPLE: If procedure report indicates adequate bowel preparation: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.2.08:** **Was the cecum reached during the colonoscopy?**

PURPOSE: To indicate whether or not the procedure notes report that the cecum was reached during the colonoscopy.

LENGTH: 1

FIELD LOCATION: 210

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.2.01 (Test 2 performed) = 4 (Colonoscopy); otherwise, leave blank.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: The procedure report must explicitly state that the cecum was reached or not reached during the colonoscopy in order to report 1 (Yes) or 2 (No); otherwise, report 9 (Unknown).

If Item 6.2.08 is 2 (No), then Item 6.2.09 (Test 2 outcome) should be coded as 2 (Incomplete/Inadequate).

EXAMPLE: If cecum was not reached: 2

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.01 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.2.09:** **Test 2 outcome**

PURPOSE: To indicate if the test reported in Item 6.2.01 was complete.

LENGTH: 1

FIELD LOCATION: 211

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.2.01 (Test 2 performed) is not 0 = (None).

If Item 6.2.05 (Result of Test 2) = 4 (Inadequate/Incomplete test with no findings), then Item 6.2.09 should = 2 (Incomplete).

If Item 6.2.05 (Result of Test 2) = 5 (FOBT/FIT/Other Test Performed Negative) or 6 (FOBT/FIT/Other Test Performed Positive), then Item 6.2.09 should = 1 (Complete).

If Item 6.2.07 (Bowel Prep Adequacy) = 2 (No), then Item 6.2.09 should = 2 (Incomplete).

If Item 6.2.08 (Cecum reached) = 2 (No), then Item 6.2.09 should = 2 (Incomplete).

CONTENTS: 1 = Complete
2 = Incomplete/Inadequate

EXPLANATION: Each test provided should have a specific result that is reported in Item 6.2.05. If the test was completed satisfactorily, report 1 (Complete).

If there were circumstances that prevented the test from being performed satisfactorily such as an obstruction, inadequate bowel prep, or the cecum was not reached, then report 2 (Incomplete/Inadequate).

If there are multiple polyps, and some of those polyps are extremely small (< 5mm), it is acceptable for the provider to choose not to remove the smaller polyps. In these instances, the Test Outcome would be considered 1 (Complete). If the recommendation of a repeat colonoscopy in 3-6 months is made, then that procedure would begin a new cycle where the indication (Item 6.0) would be reported as 2 (Surveillance).

If the provider recommends an immediate repeat exam (or additional tests needed to come to a Final Diagnosis) due to the incomplete, or non-removal of a significant polyp, then report 2 (Incomplete/Inadequate). Report the repeat exam (or additional tests needed) as Test 3.

EXAMPLE: If the colonoscopy is considered complete: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.2.10:** **Recommended next follow-up procedure within this cycle after test 2.**

PURPOSE: To indicate the next recommended procedure following the completion of Test 2.

LENGTH: 1

FIELD LOCATION: 212

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.2.01 (Test 2 performed) is not = 0 (None).

CONTENTS: 1 = Sigmoidoscopy
2 = Colonoscopy
3 = DCBE
4 = Surgery to complete diagnosis
7 = Other
8 = None (cycle is complete)

EXPLANATION: Once Test 2 is completed, the next recommended procedure within the screening cycle should be reported. The next recommended test within the screening cycle should either be a diagnostic test to follow-up a positive initial screening test or another screening test where the first and second screening tests were incomplete or inconclusive.

If the next recommended procedure for the client is surgery to complete the diagnosis, indicate 4 (Surgery). Items 8.1 and 8.2 should then be completed, along with any final diagnosis and treatment data where applicable. No further procedures (Items 6.3.01 or 6.4.01) should be reported. Items 6.3.01 and 6.4.01 should be completed with 0 (None).

If Test 2 is normal and the recommended screening or surveillance test for the next cycle is FOBT or FIT, then indicate 8 (None). The screening cycle should be considered complete and the next FOBT or FIT should begin a new CCDE record. Items 6.3.01 and 6.4.01 should be completed with 0 (None).

There may be rare instances in which it is appropriate for an FOBT or FIT to be reported as Test 3. In these instances Item 6.2.10 should be reported as 7 (Other). Item 6.2.11 (Other recommended test, specify) should be completed to indicate FOBT or FIT as the recommended next test within the cycle. These instances may include:

* FOBT or FIT card could not be read by the lab
* Client did not perform FOBT or FIT correctly
* An FOBT or FIT is recommended as follow-up to an incomplete or inconclusive colonoscopy that cannot be repeated

EXAMPLE: If a DCBE is recommended as the next procedure within this clients “cycle”: 3

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.2.11:** **Other recommended test, specify**

PURPOSE: To specify the Other test recommended in Item 6.2.10.

LENGTH: 40

FIELD LOCATION: 213 - 252

TYPE: Free text.

SKIP PATTERN: This field should be completed when Item 6.2.10 is reported as 7 (Other); otherwise, leave blank.

EXPLANATION: This field captures the type of “other” test indicated in Item 6.2.10. Use this item appropriately. Reclaiming inappropriate “other” responses is time consuming and could potentially result in the loss of valuable data.

EXAMPLE: If the next recommended test is a virtual colonoscopy: virtual colonoscopy

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.3.01:** **Test 3 performed**

PURPOSE: To indicate the third test received by the client within the current cycle.

LENGTH: 1

FIELD LOCATION: 253

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 5.2 (Screening Adherence) = 1 (Test Performed).

CONTENTS: 0 = None
3 = Sigmoidoscopy
4 = Colonoscopy
5 = Double-contrast Barium Enema (DCBE)
7 = Other

EXPLANATION: This field should be reported with the third test received by the client within the current cycle.

EXAMPLE: If the third test provided to the client is a DCBE: 5

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.3.02:** **Test 3 performed – Other specify**

PURPOSE: To specify the type of “other” test indicated in Item 6.3.01 (Test 3).

LENGTH: 40

FIELD LOCATION: 254 - 293

TYPE: Free text

SKIP PATTERN: This field should be completed when Item 6.3.01 (Test 3 performed) = 7 (Other); otherwise, leave blank.

EXPLANATION: This field captures the type of “other” test indicated in Item 6.3.01. Use this item appropriately. Reclaiming inappropriate “other” responses is time consuming and could potentially result in the loss of valuable data.

EXAMPLE: If a virtual colonoscopy is performed: virtual colonoscopy

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.3.03:** **Date of Test 3**

PURPOSE: To specify the date of the third test.

LENGTH: 8

FIELD LOCATION: 294 - 301

TYPE: Date

SKIP PATTERN: This field should be completed when Item 6.3.01 (Test 3 performed) is not = 0 (None).

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is month from 01 to 12, DD is the day from 01 to 31, and YYYY is the year of the test, including the century. If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 08 2010). This field should not be left completely blank if a second test was performed.

EXPLANATION: This field captures the date that Test 3 is performed.

EXAMPLE: If a colonoscopy is performed on August 1, 2010: 08012010

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.3.04:** **Provider specialty**

PURPOSE: To report the specialty of the clinician providing the third test.

LENGTH: 2

FIELD LOCATION: 302 - 303

TYPE: Numeric - right justify

SKIP PATTERN: This field should be completed when Item 6.3.01 (Test 3 performed) is not = 0 (None).

CONTENTS: 1 = General practitioner
 2 = Internist
 3 = Family practitioner
 4 = Gastroenterologist
 5 = General surgeon
 6 = Colorectal surgeon
 7 = Licensed practical nurse
 8 = Registered nurse
 9 = Nurse practitioner
10 = Physician assistant
12 = Radiologist
13 = Obstetrician/Gynecologist (OB/GYN)
99 = Unknown

EXPLANATION: This field should capture the medical practice specialty of the provider who performed or provided the first test reported in Item 6.3.01.

EXAMPLE: If the provider specialty for the third test is a general surgeon: 5

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.3.05:** **Result of Test 3**

PURPOSE: To specify the results of Test 3.

LENGTH: 1

FIELD LOCATION: 304

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.3.01 (Test 3 performed) is not = 0 (None).

If Item 6.3.01 = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE), then Item 6.3.05 must = 1 - 4, 7 or 9.

If Item 6.3.01 = 7 (Other), then Item 6.3.05 must be reported using the result that is appropriate for the test performed and specified in Item 6.3.02.

CONTENTS: 1 = Normal/Negative/Diverticulosis/Hemorrhoids
2 = Other finding not suggestive of cancer or polyp(s)
3 = Polyp(s), or Lesion(s) suspicious for cancer
4 = Inadequate/Incomplete test with no findings
5 = FOBT/FIT/Other Test Performed Negative
6 = FOBT/FIT/Other Test Performed Positive
7 = Pending
9 = Unknown

EXPLANATION: If more than one result is noted on the medical chart, then report the most severe.

A response of 2 (Other finding not suggestive of cancer or polyp(s) should be used when the endoscopy report indicates a specific finding, but the finding is not a cancerous lesion or a polyp.

A result of 4 (Inadequate/Incomplete) should only be reported when the endoscopy report notes that an exam was started but was incomplete or inadequate, and does not report any specific findings. Incomplete or inadequate tests may occur due to client discomfort or distress, bowel obstruction, inadequate bowel preparation (the bowel was not adequately cleared of fecal material) or physician fatigue.

 If the endoscopy report notes specific findings, even during an incomplete or inadequate test, then the test result should reflect the observations and be reported using response options 1, 2 or 3.

 When a Test Result = 4 (Inadequate/Incomplete), then Item 6.1.09 (Test Outcome) should be coded as 2 (Incomplete/Inadequate) and an additional test should be recommended.

EXAMPLE: If result of the colonoscopy is normal: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.3.06:** **Was a biopsy/polypectomy performed during the endoscopy?**

PURPOSE: To indicate if a biopsy or polypectomy was performed during the sigmoidoscopy or colonoscopy.

LENGTH: 1

FIELD LOCATION: 305

TYPE: Numeric

SKIP PATTERN: If Item 6.3.06 = 1 (Yes), then Item 7.1 (Histology of most severe polyp/lesion) must be completed.

Leave blank if 6.3.01 = 0, 5 or 7.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: This field should only be completed if the third test provided is either a colonoscopy or sigmoidoscopy.

If a biopsy was performed (1), then Item 7.1 (Histology of most severe polyp/lesion) must be completed.

EXAMPLE: If a polypectomy was performed during a colonoscopy: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.3.07:** **Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE?**

PURPOSE: To indicate the adequacy of the bowel preparation for a sigmoidoscopy, colonoscopy or DCBE.

LENGTH: 1

FIELD LOCATION: 306

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.3.01 (Test 3 performed) = 3 (Sigmoidoscopy), 4 (Colonoscopy), 5 (DCBE) or 7 (Other); otherwise, leave blank.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: Adequacy of the bowel preparation will be determined by the clinician performing the test. A response of 1 (Yes) or 2 (No) can only be reported if the procedure report explicitly states that the bowel preparation was adequate or inadequate; otherwise report 9 (Unknown).

If Test 3 = 7 (Other) and the procedure does not require bowel preparation, please code the adequacy of bowel preparation as 9 (Unknown).

If the adequacy of bowel preparation = 2 (No), then Item 6.3.09 (Test outcome) should be coded as 2 (Incomplete/Inadequate).

 The standardized colonoscopy reporting and data system (CO-RADs) quality measure for adequacy of bowel prep is described as adequacy to detect polyps > 5 mm.

EXAMPLE: If procedure report indicates adequate bowel preparation: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.3.08:** **Was the cecum reached during the colonoscopy?**

PURPOSE: To indicate whether or not the procedure notes report that the cecum was reached during the colonoscopy.

LENGTH: 1

FIELD LOCATION: 307

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.3.01 (Test 3 performed) = 4 (Colonoscopy); otherwise, leave blank.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: The procedure report must explicitly state that the cecum was reached or not reached during the colonoscopy in order to report 1 (Yes) or 2 (No); otherwise, report 9 (Unknown).

If Item 6.3.08 is 2 (No), then Item 6.3.09 (Test 3 outcome) should be coded as 2 (Incomplete/Inadequate).

EXAMPLE: If cecum was not reached: 2

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.01 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.3.09:** **Test 3 outcome**

PURPOSE: To indicate if the third test was complete.

LENGTH: 1

FIELD LOCATION: 308

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.3.01 (Test 3 performed) is not = 0 (None).

If Item 6.3.05 (Result of Test 3) = 4 (Inadequate/Incomplete test with no findings), then Item 6.3.09 should = 2 (Incomplete).

If Item 6.3.05 (Result of Test 2) = 5 (FOBT/FIT/Other Test Performed Negative) or 6 (FOBT/FIT/Other Test Performed Positive), then Item 6.3.09 should = 1 (Complete).

If Item 6.3.07 (Bowel Prep Adequacy) = 2 (No), then Item 6.3.09 should = 2 (Incomplete).

If Item 6.3.08 (Cecum reached) = 2 (No), then Item 6.3.09 should = 2 (Incomplete).

CONTENTS: 1 = Complete
2 = Incomplete/Inadequate

EXPLANATION: Each test provided should have a specific result that is reported in Item 6.3.05. If the test was completed satisfactorily, report 1 (Complete).

If there were circumstances that prevented the test from being performed satisfactorily such as an obstruction, inadequate bowel prep, or the cecum was not reached, then report 2 (Incomplete/Inadequate).

If there are multiple polyps, and some of those polyps are extremely small (< 5mm), it is acceptable for the provider to choose not to remove the smaller polyps. In these instances, the Test Outcome would be considered 1 (Complete). If the recommendation of a repeat colonoscopy in 3-6 months is made, then that procedure would begin a new cycle where the indication (Item 6.0) would be reported as 2 (Surveillance).

If the provider recommends an immediate repeat exam (or additional tests needed to come to a Final Diagnosis) due to the incomplete, or non-removal of a significant polyp, then report 2 (Incomplete/Inadequate). Report the repeat exam (or additional tests needed) as Test 4.

EXAMPLE: If the colonoscopy is considered complete: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.3.10:** **Recommended next follow-up procedure within this cycle after test 3.**

PURPOSE: To indicate the next recommended procedure following the completion of Test 3.

LENGTH: 1

FIELD LOCATION: 309

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.3.01 (Test 3 performed) is not = 0 (None).

CONTENTS: 1 = Sigmoidoscopy
2 = Colonoscopy
3 = DCBE
4 = Surgery to complete diagnosis
7 = Other
8 = None (cycle is complete)

EXPLANATION: Once Test 3 is completed, the next recommended procedure within the screening cycle should be reported. The next recommended test within the screening cycle would either be a diagnostic test to follow-up a positive initial screening test or another screening test where Test 1 through Test 3 screening tests were incomplete or inconclusive.

If the next recommended procedure for the client is surgery to complete the diagnosis, indicate 4 (Surgery). Items 8.1 and 8.2 should then be completed, along with any final diagnosis and treatment data where applicable. No further procedures (Item 6.4.01) should be reported. Item 6.4.01 will be completed with 0 (None).

If Test 3 is normal and the recommended screening or surveillance test for the next cycle is FOBT or FIT, then indicate 8 (None). The screening cycle should be considered complete and the next FOBT or FIT should begin a new CCDE record. Item 6.4.01 should be completed with 0 (None).

There may be rare instances in which it is appropriate for an FOBT or FIT to be reported as Test 4. In these instances Item 6.3.10 should be reported as 7 (Other). Item 6.3.11 (Other recommended test, specify) should be completed to indicate FOBT or FIT as the recommended next test within the cycle. These instances may include:

* FOBT or FIT card could not be read by the lab
* Client did not perform FOBT or FIT correctly
* An FOBT or FIT is recommended as follow-up to an incomplete or inconclusive colonoscopy that cannot be repeated

EXAMPLE: If a DCBE is recommended as the next procedure within this clients “cycle”: 3

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.3.11:** **Other recommended test, specify**

PURPOSE: To specify the Other test recommended in Item 6.3.10.

LENGTH: 40

FIELD LOCATION: 310 - 349

TYPE: Free text.

SKIP PATTERN: This field should be completed when Item 6.3.10 is reported as 7 (Other). Otherwise, leave blank.

EXPLANATION: This field captures the type of “other” test indicated in Item 6.3.10. Use this item appropriately. Reclaiming inappropriate “other” responses is time consuming and could potentially result in the loss of valuable data.

EXAMPLE: If the next recommended test is a virtual colonoscopy: virtual colonoscopy

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.4.01:** **Test 4 performed**

PURPOSE: To indicate the fourth test received by the client within the current cycle.

LENGTH: 1

FIELD LOCATION: 350

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 5.2 (Screening Adherence) = 1 (Test Performed).

CONTENTS: 0 = None
3 = Sigmoidoscopy
4 = Colonoscopy
5 = Double-contrast Barium Enema (DCBE)
7 = Other

EXPLANATION: This field should be reported with the fourth test received by the client within the current cycle.

EXAMPLE: If the fourth test provided to the client is a DCBE: 5

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.4.02:** **Test 4 performed – Other specify**

PURPOSE: To specify the type of “other” test indicated in Item 6.4.01 (Test 4).

LENGTH: 40

FIELD LOCATION: 351 - 390

TYPE: Free text

SKIP PATTERN: This field should be completed when Item 6.4.01 (Test 4 performed) = 7 (Other). Otherwise, leave blank.

EXPLANATION: This field captures the type of “other” test indicated in Item 6.4.01. Use this item appropriately. Reclaiming inappropriate “other” responses is time consuming and could potentially result in the loss of valuable data.

EXAMPLE: If a virtual colonoscopy is performed: virtual colonoscopy

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.4.03:** **Date of Test 4**

PURPOSE: To specify the date of the fourth test.

LENGTH: 8

FIELD LOCATION: 391 - 398

TYPE: Date

SKIP PATTERN: This field should be completed when Item 6.4.01 (Test 4 performed) is not = 0 (None).

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is month from 01 to 12, DD is the day from 01 to 31, and YYYY is the year of the test, including the century. If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 08 2010). This field should not be left completely blank if a second test was performed.

EXPLANATION: This field captures the date that Test 4 is performed.

EXAMPLE: If a colonoscopy is performed on August 1, 2010: 08012010

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.4.04:** **Provider specialty**

PURPOSE: To report the specialty of the clinician providing the fourth test.

LENGTH: 2

FIELD LOCATION: 399 - 400

TYPE: Numeric - right justify

SKIP PATTERN: This field should be completed when Item 6.4.01 (Test 4 performed) is not = 0 (None).

CONTENTS: 1 = General practitioner
 2 = Internist
 3 = Family practitioner
 4 = Gastroenterologist
 5 = General surgeon
 6 = Colorectal surgeon
 7 = Licensed practical nurse
 8 = Registered nurse
 9 = Nurse practitioner
10 = Physician assistant
12 = Radiologist
13 = Obstetrician/Gynecologist (OB/GYN)
99 = Unknown

EXPLANATION: This field should capture the medical practice specialty of the provider who performed or provided the first test reported in Item 6.4.01.

EXAMPLE: If the provider specialty for the fourth test is a general surgeon: 5

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.4.05:** **Result of Test 4**

PURPOSE: To specify the results of Test 4.

LENGTH: 1

FIELD LOCATION: 401

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.4.01 (Test 4 performed) is not = 0 (None).

If Item 6.4.01 = 3 (Sigmoidoscopy), 4 (Colonoscopy) or 5 (DCBE), then Item 6.4.05 must = 1 - 4, 7 or 9.

If Item 6.4.01 = 7 (Other), then Item 6.4.05 must be reported using the result that is appropriate for the test performed and specified in Item 6.4.02.

CONTENTS: 1 = Normal/Negative/Diverticulosis/Hemorrhoids
2 = Other finding not suggestive of cancer or polyp(s)
3 = Polyp(s), or Lesion(s) suspicious for cancer
4 = Inadequate/Incomplete test with no findings
5 = FOBT/FIT/Other Test Performed Negative
6 = FOBT/FIT/Other Test Performed Positive
7 = Pending
9 = Unknown

EXPLANATION: If more than one result is noted on the medical chart, then report the most severe.

A response of 2 (Other finding not suggestive of cancer or polyp(s) should be used when the endoscopy report indicates a specific finding, but the finding is not a cancerous lesion or a polyp.

A result of 4 (Inadequate/Incomplete) should only be reported when the endoscopy report notes that an exam was started but was incomplete or inadequate, and does not report any specific findings. Incomplete or inadequate tests may occur due to client discomfort or distress, bowel obstruction, inadequate bowel preparation (the bowel was not adequately cleared of fecal material) or physician fatigue.

 If the endoscopy report notes specific findings, even during an incomplete or inadequate test, then the test result should reflect the observations and be reported using response options 1, 2 or 3.

 When a Test Result = 4 (Inadequate/Incomplete), then Item 6.1.09 (Test Outcome) should be coded as 2 (Incomplete/Inadequate) and an additional test should be recommended.

EXAMPLE: If result of the colonoscopy is normal: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.4.06:** **Was a biopsy/polypectomy performed during the endoscopy?**

PURPOSE: To indicate if biopsy or polypectomy was performed during the sigmoidoscopy or colonoscopy.

LENGTH: 1

FIELD LOCATION: 402

TYPE: Numeric

SKIP PATTERN: If Item 6.4.06 = 1 (Yes), then Item 7.1 (Histology of most severe polyp/lesion) must be completed.

Leave blank if 6.4.01 = 0, 5 or 7.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: This field should only be completed if the fourth test provided is either a colonoscopy or sigmoidoscopy.

If a biopsy was performed (1), then Item 7.1 (Histology of most severe polyp/lesion) must be completed.

EXAMPLE: If a polypectomy was performed during a colonoscopy: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.4.07:** **Was the bowel preparation considered adequate by the clinician performing the endoscopy or DCBE?**

PURPOSE: To indicate the adequacy of the bowel preparation for a sigmoidoscopy, colonoscopy or DCBE.

LENGTH: 1

FIELD LOCATION: 403

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.4.01 (Test 4 performed) = 3 (Sigmoidoscopy), 4 (Colonoscopy), 5 (DCBE) or 7 (Other); otherwise, leave blank.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: Adequacy of the bowel preparation will be determined by the clinician performing the test. A response of 1 (Yes) or 2 (No) can only be reported if the procedure report explicitly states that the bowel preparation was adequate or inadequate; otherwise report 9 (Unknown).

If Test 1 = 7 (Other) and the procedure does not require bowel preparation, please code the adequacy of bowel preparation as 9 (Unknown).

If the adequacy of bowel preparation = 2 (No), then Item 6.4.09 (Test outcome) should be coded as 2 (Incomplete/Inadequate).

 The standardized colonoscopy reporting and data system (CO-RADs) quality measure for adequacy of bowel prep is described as adequacy to detect polyps > 5 mm.

EXAMPLE: If procedure report indicates adequate bowel preparation: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.4.08:** **Was the cecum reached during the colonoscopy?**

PURPOSE: To indicate whether or not the procedure notes report that the cecum was reached during the colonoscopy.

LENGTH: 1

FIELD LOCATION: 404

TYPE: Numeric

SKIP PATTERN: This field should be completed if Item 6.4.01 (Test 4 performed) = 4 (Colonoscopy); otherwise, leave blank.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: The procedure report must explicitly state that the cecum was reached or not reached during the colonoscopy in order to report 1 (Yes) or 2 (No); otherwise, report 9 (Unknown).

If Item 6.4.08 is 2 (No), then Item 6.4.09 (Test 4 outcome) should be coded as 2 (Incomplete/Inadequate).

EXAMPLE: If cecum was not reached: 2

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.01 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.4.09:** **Test 4 outcome**

PURPOSE: To indicate if the fourth test was complete.

LENGTH: 1

FIELD LOCATION: 405

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.4.01 (Test 4 performed) is not = 0 (None).

If Item 6.4.05 (Result of Test 4) = 4 (Inadequate/Incomplete test with no findings), then Item 6.4.09 should = 2 (Incomplete).

If Item 6.4.05 (Result of Test 2) = 5 (FOBT/FIT/Other Test Performed Negative) or 6 (FOBT/FIT/Other Test Performed Positive), then Item 6.4.09 should = 1 (Complete).

If Item 6.4.07 (Bowel Prep Adequacy) = 2 (No), then Item 6.4.09 should = 2 (Incomplete).

If Item 6.4.08 (Cecum reached) = 2 (No), then Item 6.4.09 should = 2 (Incomplete).

CONTENTS: 1 = Complete
2 = Incomplete/Inadequate

EXPLANATION: Each test provided should have a specific result that is reported in Item 6.4.05. If the test was completed satisfactorily, report 1 (Complete).

If there were circumstances that prevented the test from being performed satisfactorily such as an obstruction, inadequate bowel prep, or the cecum was not reached, then report 2 (Incomplete/Inadequate).

If there are multiple polyps, and some of those polyps are extremely small (< 5mm), it is acceptable for the provider to choose not to remove the smaller polyps. In these instances, the Test Outcome would be considered 1 (Complete). If the recommendation of a repeat colonoscopy in 3-6 months is made, then that procedure would begin a new cycle where the indication (Item 6.0) would be reported as 2 (Surveillance).

EXAMPLE: If the colonoscopy is considered complete: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **6.4.10:** **Recommended next follow-up procedure within this cycle after test 4.**

PURPOSE: To indicate the next recommended procedure following the completion of Test 4.

LENGTH: 1

FIELD LOCATION: 406

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 6.4.01 (Test 4 performed) is not = 0 (None).

CONTENTS: 4 = Surgery to complete diagnosis
8 = None (cycle is complete)

EXPLANATION: Once Test 4 is completed, the next recommended procedure within the screening cycle should be reported.

If the next recommended procedure for the client is surgery to complete the diagnosis, indicate 4 (Surgery). Items 8.1 and 8.2 should then be completed, along with any final diagnosis and treatment data where applicable.

If Test 4 was normal and the next test recommended is a screening exam (FOBT or FIT), indicate 8 (None). The screening cycle would be completed and the new screening test will begin a new CCDE record.

EXAMPLE: If no further tests are recommended within this clients “cycle”: 8

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **7.1: Histology of the most severe polyp or lesion**

PURPOSE: Report the worst histology of all biopsies and polypectomies performed during this cycle.

LENGTH: 2

FIELD LOCATION: 407 - 408

TYPE: Numeric - right justify

SKIP PATTERN: This field should be completed if a biopsy or polypectomy was performed during any of Test 1 – 4 [Item 6.x.06 = 1 (Yes)].

CONTENTS: 1 = Normal or other non-polyp histology
 2 = Non-adenomatous polyp (inflammatory, hamartomatous, etc.)
 3 = Hyperplastic polyp
 4 = Adenoma, NOS (no high grade dysplasia noted)
 5 = Adenoma, tubular (no high grade dysplasia noted)
 6 = Adenoma, mixed tubular villous (no high grade dysplasia
 noted)
 7 = Adenoma, villous (no high grade dysplasia noted)
 8 = Adenoma, serrated (no high grade dysplasia noted)
 9 = Adenoma with high grade dysplasia (includes in situ
 carcinoma)
10 = Adenocarcinoma, invasive
11 = Cancer, other
99 = Unknown/other lesions ablated, not retrieved or confirmed

EXPLANATION: Report the most severe histology result found across all pathology for Test 1 through Test 4 when a biopsy or polypectomy was performed during endoscopy. Do not include histology results from surgical resection. Histology from surgical resection should be reported in Item 8.1.

Do not update or change the histology reported for this variable if polyp with high grade dysplasia is determined to be cancer during a subsequent surgery.

If the worst histology includes any of the adenoma diagnoses (4-11), then Items 7.2 and 7.3 must be completed.

EXAMPLE: If the histology for the polyp/lesion removed is carcinoma: 11

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

The following table was designed to assist grantees in mapping specific ICD-O morphology codes to the CCDE Histology categories.

| **CCDE Colorectal Histology Categories** | **International Classification of Disease for Oncology, 3rd Edition, Acceptable Morphology Codes and Terminology from Common Codes** |
| --- | --- |
| **1=Normal or other non-polyp histology** | **n/a** |
| **2=Non-adenomatous polyp (inflammatory, hamartomatous, etc.)** | **n/a** |
| **3=Hyperplastic polyp** | **n/a** |
| **4=Adenoma, NOS (no high-grade dysplasia noted)** | **8140-8147, 8160-8162, 8180-8210, 8212, 8214-8221, 8250-8260, 8262, 8264-8506, 8520-8550, 8560, 8570-8573, 8940-8941 *(with behavior codes of /0)*** |
| 8140/0 | Adenoma, NOS |
| 8210/0 | Adenomatous polyp, NOS |
|   | 8212/0 | Flat adenoma |
|   | 8220/0 | Adenomatous polyposis coli |
|   | 8221/0 | Multiple adenomatous polyps |
| **5=Adenoma, tubular (no high-grade dysplasia noted)** | **8211 *(with behavior code of /0)*** |
|  | 8211/0 | Tubular adenoma, NOS |
| **6=Adenoma, mixed tubular villous (no high-grade dysplasia noted)** | **8263 *(with behavior code of /0)*** |
|  | 8263/0 | Tubulovillous adenoma, NOS |
| **7=Adenoma, villous (no high-grade dysplasia noted)** | **8261 *(with behavior code of /0)*** |
|  | 8261/0 | Villous adenoma, NOS |
| **8=Adenoma, serrated (no high-grade dysplasia noted)** | **8213 *(with behavior code of /0)*** |
|  | 8213/0 | Serrated adenoma |
| **9=Adenoma with high-grade dysplasia (includes in situ carcinoma)** | **8140-8147, 8160-8162, 8180-8221, 8250-8506, 8520-8550, 8560, 8570-8573, 8940-8941 *(with behavior codes of /2)*** |
|   | 8140/2 | Adenocarcinoma in situ, NOS |
|   | 8210/2 | Adenocarcinoma in situ in adenomatous polyp |
|   | 8261/2 | Adenocarcinoma in situ in villous adenoma |
|   | 8263/2 | Adenocarcinoma in situ in tubulovillous adenoma |
| **10=Adenocarcinoma, invasive** | **8140-8147, 8160-8162, 8180-8221, 8250-8506, 8510, 8520-8550, 8560, 8570-8573, 8940-8941 *(with behavior codes of /3)*** |
|   | 8140/3 | Adenocarcinoma, NOS |
|   | 8141/3 | Scirrhous adenocarcinoma |
|   | 8210/3 | Adenocarcinoma in adenomatous polyp |
|  **10=Adenocarcinoma, invasive (continued)** | 8211/3 | Tubular adenocarcinoma |
|   | 8214/3 | Parietal cell carcinoma |
|   | 8220/3 | Adenocarcinoma in adenomatous polyposis coli |
|   | 8221/3 | Adenocarcinoma in multiple adenomatous polyps |
|   | 8260/3 | Papillary adenocarcinoma, NOS |
|   | 8261/3 | Adenocarcinoma in villous adenoma |
|   | 8262/3 | Villous adenocarcinoma |
|   | 8263/3 | Adenocarcinoma in tubulovillous adenoma |
|   | 8470/3 | Mucinous cystadenocarcinoma, NOS |
|   | 8480/3 | Mucinous adenocarcinoma |
|   | 8481/3 | Mucin-producing adenocarcinoma |
|   | 8490/3 | Signet ring cell carcinoma |
|   | 8560/3 | Adenosquamous carcinoma |
|   | 8570/3 | Adenocarcinoma with squamous metaplasia |
|   | 8571/3 | Adenocarcinoma with cartilaginous and osseous metaplasia |
|   | 8940/3 | Mixed tumor, malignant, NOS |
|   | 8941/3 | Carcinoma in pleomorphic adenoma |
| **11=Cancer, other** | **8000-8139, 8148-8159, 8163-8179, 8222-8249, 8507-8509, 8511-8519, 8551-8559, 8561-8569, 8574-8939, 8942-9989 *(with behavior codes of /3)*** |
|   | 8001/3 | Tumor cells, malignant |
|   | 8002/3 | Malignant tumor, small cell type |
|   | 8004/3 | Malignant tumor, spindle cell type |
|   | 8005/3 | Malignant tumor, clear cell type |
|   | 8050/3 | Papillary carcinoma, NOS |
|   | 8070/3 | Squamous cell carcinoma, NOS. |
|   | 8240/3 | Carcinoid tumor, NOS |
|   | 8249/3 | Atypical carcinoid tumor |

ITEM NO / NAME: **7.2: Total number of adenomatous polyps/lesions**

PURPOSE: To indicate the total number of adenomatous polyps/lesions removed or biopsied through all endoscopy procedures during the client’s “cycle”. Do not report specimens from surgical resections.

LENGTH: 2

FIELD LOCATION: 409 - 410

TYPE: Numeric - right justify

SKIP PATTERN: If Item 7.1 (Histology of most severe polyp/lesion) is an adenoma or cancer (4-11), then Item 7.2 should be completed; otherwise, leave blank.

CONTENTS: 01 = One adenomatous polyp/lesion removed or biopsied
02 = Two adenomatous polyps/lesions removed or biopsied
…
97 = ≥ Ninety-seven adenomatous polyps/lesions removed or
 biopsied
98 = At least one adenomatous polyp/lesion removed or biopsied,
 exact number not known
99 = Unknown

EXPLANATION: The actual number of adenomatous polyps or lesions removed should be acquired for each test provided. In the case of a large cancer or lesion which cannot be removed during endoscopy, the endoscopist may biopsy the area to obtain a specimen for pathology. Include these specimens when counting the total number of all adenomatous polyps or lesions removed or biopsied and report in Item 7.2.

When more than 97 adenomatous polyps or lesions are removed or biopsied during endoscopy, report 97 (≥ 97 polyps/lesions).

If the report indicates adenomatous polyps or lesions were removed or biopsied, but no definite account of the number removed is available, indicate 98 (At least one polyp/lesion, exact number not known).

If it is unknown whether any adenomatous polyps or lesions were removed or biopsied, code 99 (Unknown).

EXAMPLE: If 8 adenomatous polyps/lesions are noted: 08

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **7.3: Size of largest adenomatous polyp/lesion**

PURPOSE: To report the size of the largest adenomatous polyp or lesion reported across all endoscopy procedures performed within the cycle. Do not report specimens from surgical resections.

LENGTH: 1

FIELD LOCATION: 411

TYPE: Numeric – right justify

SKIP PATTERN: If Item 7.1 (Histology of most severe polyp/lesion) is an adenoma or cancer (4-11), then Item 7.3 should be completed; otherwise, leave blank.

CONTENTS: 1 = < 1 cm
2 = ≥ 1 cm
9 = Unknown

EXPLANATION: Report the diameter of the polyp/lesion in centimeters (cm) or the longest dimension of the polyp/lesion. This should be the size of the actual polyp and not the size of the biopsy specimen submitted for pathology. Do not include information from any surgical resection.

There may be instances when a lesion is biopsied, but not removed during endoscopy. The size of such lesions should also be taken into consideration when reporting the size of the largest adenomatous polyp or lesion.

Size may be found on both the endoscopy and pathology reports, but size from the endoscopy report is preferred. If the specimen is not intact when sent to the pathology lab, do not report specimen size from the pathology report.

EXAMPLE: If the size of the lesion is 2 cm: 2

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **8.1: Histology from surgical resection**

PURPOSE: To report the worst histopathology from the surgical resection reported in Item 6.x.10 (where x is either the 1st, 2nd, 3rd or 4th test reported in Section 6) if the client underwent surgery to complete the diagnosis.

LENGTH: 2

FIELD LOCATION: 412 - 413

TYPE: Numeric - right justify

SKIP PATTERN: If Item 6.x.10 is 4 (Surgery to complete diagnosis), then this field should be completed; otherwise, leave blank.

CONTENTS: 0 = Surgery recommended but not performed
 1 = Normal or other non-polyp histology
 2 = Non-adenomatous polyp (inflammatory, hamartomatous, etc.)
 3 = Hyperplastic polyp
 4 = Adenoma, NOS (no high grade dysplasia noted)
 5 = Adenoma, tubular (no high grade dysplasia noted)
 6 = Adenoma, mixed tubular villous (no high grade dysplasia
 noted)
 7 = Adenoma, villous (no high grade dysplasia noted)
 8 = Adenoma, serrated (no high grade dysplasia noted)
 9 = Adenoma with high grade dysplasia (includes in situ
 carcinoma)
10 = Adenocarcinoma, invasive
11 = Cancer, other
99 = Unknown/other lesions ablated, not retrieved or confirmed

 **NOTE:** For guidance on converting ICD-O morphology to CCDE histology from surgical resection, refer to the table following Item 7.1 (Histology of most severe polyp/lesion).

EXPLANATION: Most often, if a polyp is detected during endoscopy, it can be removed during the endoscopy and the client will not need surgery to complete the diagnosis. On some occasions, if the polyp is large or the lesion is suspicious for cancer, a biopsy will be taken, but the lesion will not be removed in its entirety during the endoscopy. Instead, it will be removed during a subsequent surgery to complete the diagnosis.

Report the worst histopathological diagnosis made from surgical resection. The response options are listed in general order of severity. If more than one surgical resection was performed to obtain a final diagnosis, all of the resections performed should be considered when determining the worst histopathological diagnosis.

If surgery was recommended in Item 6.x.10 (Recommended next follow-up procedure within the cycle), but was not performed, code 0 (Surgery recommended but not performed). If no surgery was recommended in Item 6.x.10, then Item 8.1 should be left blank.

If the histology from surgical resection is not found in the pathology report, indicate 99 (Unknown).

Use the histology from surgical resection in conjunction with Item 7.1 (Histology of most severe polyp/lesion) when reporting the final diagnosis (Item 9.02).

EXAMPLE: If the histology for the polyp/lesion removed is cancer, other: 11

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **8.2: Date surgery performed**

PURPOSE: To indicate the date of the surgical resection to complete the diagnosis.

LENGTH: 8

FIELD LOCATION: 414 - 421

TYPE: Date

SKIP PATTERN: If 8.1 = 1-11, 99 then complete this field; otherwise, leave blank.

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is the month of surgery from 01 to 12, DD is the day of surgery from 01 to 31, and YYYY is the year of the surgery, including the century. If just the year is known, blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 08 2010).

EXPLANATION: This field captures the date that the surgery to complete diagnosis was performed. If more than one surgical resection was performed to obtain a final diagnosis, then report the date of the surgery which provided the final diagnosis (Item 9.02).

Frequently, the screening cycle will conclude with endoscopy and surgery will not be required to complete the diagnosis. Surgery to complete the final diagnosis will only be performed if a suspicious polyp or lesion could not be completely removed during endoscopy.

If Item 8.1 = 0 (Surgery recommended but not performed), then this field should be left blank.

EXAMPLE: If a surgery was performed on August 1, 2010: 08012010

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **9.01:**  **Status of final diagnosis**

PURPOSE: To specify the status of final diagnosis for a cycle after all screening and diagnostic tests are performed/offered to the client.

LENGTH: 1

FIELD LOCATION: 422

TYPE: Numeric

SKIP PATTERN: This field should be completed when Item 5.2 (Screening adherence) is reported as 1 (performed); otherwise, leave blank.

CONTENTS: 1 = Complete (final diagnosis determined)
2 = Pending final diagnosis
3 = Client refused diagnostic follow-up
4 = Client lost to follow-up before final diagnosis was made
5 = Irreconcilable.

EXPLANATION: Report the status of the client’s care after all screening and diagnostic tests are performed/offered to the client.

If a client receives a single screening test, and that test is normal/negative, then complete this field as 1 (Complete).

A status of 2 (Pending final diagnosis) indicates that not all of the planned tests have been completed and therefore a final diagnosis has not yet been determined. A record should not be pending for more than one year. Such records should be monitored so that as a client’s tests are completed, and a final diagnosis is made, this field may be updated to the appropriate status of final diagnosis.

A status of 3 (Client refused diagnostic follow-up) should be reported if a client severs his or her relationship with the Program. For example, a client may decline the recommended tests, or may choose to have the tests performed by a provider outside of the Program. While such cases are simply reported to the CDC as 3 (Refused) in the CCDE file, Grantees should track more detailed information about each “refused” case.

A status of 4 (Client lost to follow-up) should be reported if prior to the completion of all recommended tests, a client moves to a location beyond the Program’s range of service delivery, or the client can no longer be located by the grantee. A status of 4 (Lost to Follow-up) should also be reported if a client dies prior to the completion of all recommended tests. Lost to follow-up should be reported when tracking efforts have been attempted in accordance with the grantee’s written protocol, but were unsuccessful. Again, while such cases are simply reported to the CDC as 4 (Lost to Follow-up) in the CCDE file, grantees should track more detailed information about each “lost” case.

All grantees must have a policy in place to define how much time can elapse before the client is considered 3 (Refused) or 4 (Lost to follow-up). The CDC realizes that in many cases attempts to contact a client occur well beyond the closure of a record as lost to follow-up or refused. In the event that these efforts are successful and the client returns to the Program after the record was closed as lost to follow-up or refused, the grantee should consult with the client’s clinician and its Medical Advisory Board to determine if the client‘s previous cycle of care should resume, or if a new cycle of care should begin.

A status of 5 (Irreconcilable) should be used for records which after clinical review, it was determined that there was no sufficient way to translate the clinical scenario into the CCDE data record. For example, a clinician might refer a client for a short-term recall instead of following the clinical guidelines for immediate diagnostic work-up. In such cases, enter “5” to indicate a cycle that has been reviewed and subsequently closed with an irreconcilable status.

It is recommended that grantees do not include irreconcilable status of final diagnosis on their CCDE data collection forms for providers to select. The intent of irreconcilable status of final diagnosis is for administrative use at your Program’s central data location, and not at the provider level. Its intended use is to help grantees manage the records in the Feedback Reports that need to be reviewed and reconciled. However, records closed using an irreconcilable status of final diagnosis will still be regarded as records with incomplete follow-up in analyses of completeness.

EXAMPLE: If status of client’s care for the current CCDE record is complete: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **9.02:**  **Final diagnosis**

PURPOSE: To specify the final diagnosis after all tests have been completed.

LENGTH: 1

FIELD LOCATION: 423

TYPE: Numeric

SKIP PATTERN: If Item 9.01 (Status of final diagnosis) is 1 (Complete), then this field should be completed; otherwise, leave blank.

CONTENTS: 1 = Normal/Negative
2 = Hyperplastic polyps
3 = Adenomatous polyp, no high grade dysplasia
4 = Adenomatous polyp with high grade dysplasia
5 = Cancer

EXPLANATION: After all screening and diagnostic tests are performed or offered to the client, report the final diagnosis that the clinician will use to determine the re-screening or surveillance test recommendation. In some cases, polyps or lesions may be removed during differing procedures, with each procedure resulting in a different histology. Report the worst diagnosis (among all procedures performed) as the final diagnosis.

If the only test performed in the screening cycle (Item 6.1.01) was an FOBT or FIT that was negative, and Item 9.01 (Status of final diagnosis) = 1 (complete), then complete this field as 1 (Normal/Negative).

Section 10 (Treatment Information) should be completed if Item 9.02 (Final Diagnosis) = 5 (Cancer). Treatment information may be completed if Item 9.02 = 4 (Adenomatous Polyp with high grade dysplasia) and treatment was recommended by the clinician.

Section 11 (Registry Information for Cancer/High Grade Dysplasia) should be completed if Item 9.02 (Final Diagnosis) = 4 (Adenomatous polyp with high grade dysplasia) or 5 (Cancer).

EXAMPLE: If the final diagnosis is Normal: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **9.03: Date of final diagnosis**

PURPOSE: To specify the date of final diagnosis.

LENGTH: 8

FIELD LOCATION: 424 - 431

TYPE: Date

SKIP PATTERN: This field should be completed if Item 9.01 (Status of final diagnosis) is 1 (Complete), 3 (Refused), 4 (Lost to follow-up) or 5 (Irreconcilable); otherwise, it should be blank.

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is the month of diagnosis from 01 to 12, DD is the day of diagnosis from 01 to 31, and YYYY is the year of diagnosis. If any part of the date is unknown, blank-fill only that part. For example, if the month and year of diagnosis are known, but the day is not, then blank-fill the day (e.g. 08 2010).

EXPLANATION: This field should indicate the date of the procedure that provided the final diagnosis (which may include the date of the “normal” screening test). If more than one procedure was performed to obtain a final diagnosis, report the date of the procedure which provided the worst histologic diagnosis. In some cases the first of multiple tests may provide the date of final diagnosis.

 If the client refused tests, or was determined to be lost to follow-up, then an administrative close-out date should be reported as the date of final diagnosis. If the client moved before all tests were completed and a final diagnosis could not be obtained, then an administrative close-out date should be reported as the date of final diagnosis.

EXAMPLE: If the date of the final pathology report is July 15, 2010: 07152010

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **9.04: Recommended screening or surveillance test for next cycle**

PURPOSE: To indicate the next recommended test for the client at the end of the “cycle”.

LENGTH: 1

FIELD LOCATION: 432

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 9.01 does not = 1.

CONTENTS: 1 = Take-home FOBT
2 = Take-home FIT
3 = Sigmoidoscopy
4 = Colonoscopy
5 = DCBE
8 = None
9 = Unknown

EXPLANATION: Report the next screening or surveillance test recommended to the client at the end of the cycle. Examples include a surveillance colonoscopy following a previous abnormal colonoscopy and/or surgery, or the next screening test recommended to the client following a normal/negative test.

If client is terminally ill, or for other reasons no further tests are recommended by the clinician, then code this item as 8 (None).

EXAMPLE: If a FOBT is recommended as the test to begin the next cycle: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **9.05: Indication for screening or surveillance test for next cycle**

PURPOSE: To report the indication for the next test recommended to the client.

LENGTH: 1

FIELD LOCATION: 433

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 9.01 (Status of final diagnosis) does not =1 (Complete).

Leave blank if Item 9.04 (Recommended screening or surveillance test for next cycle) = 8 (None) or 9 (Unknown).

CONTENTS: 1 = Screening
2 = Surveillance after a positive colonoscopy and/or surgery

EXPLANATION: If a test was recommended in Item 9.04, then the indication for the test (screening vs. surveillance) should be reported.

 Grantees should encourage their providers to make re-screening and surveillance frequency recommendations based on published guidelines, when available.

EXAMPLE: If the next recommended test is a screening test: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **9.06: Number of months before screening or surveillance test for next cycle.**

PURPOSE: To indicate the recommended interval between Item 9.03 (Date of final diagnosis) and the next recommended screening/surveillance test.

LENGTH: 3

FIELD LOCATION: 434 - 436

TYPE: Numeric - right justify

SKIP PATTERN: Leave blank if Item 9.01 does not = 1 (Complete).

Leave blank if Item 9.04 (Recommended screening or surveillance test for next cycle) = 8 (None) or 9 (Unknown).

CONTENTS: 12 = Twelve months
 13 = Thirteen months
…
180 = One hundred eighty months
999 = Unknown

EXPLANATION: If a test was recommended in Item 9.04, then the report the interval between the final diagnosis and the next test date. If Item 9.04 is reported as 8 (None) or 9 (Unknown), this field should be left blank.

EXAMPLE: If the recommended interval before the next test is two years: 24

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **9.07: Complications (1) of endoscopy or DCBE requiring observation or treatment**

PURPOSE: To indicate if there was a complication that occurred due to a DCBE or endoscopy procedure.

LENGTH: 2

FIELD LOCATION: 437 - 438

TYPE: Numeric - right justify

SKIP PATTERN: If Item 6.x.01 (Test Performed) was 3 (Sigmoidoscopy), 4 (Colonoscopy), 5 (DCBE) or 7 (Other) then this field should be completed; otherwise, leave blank.

CONTENTS: 0 = No complications reported
 1 = Bleeding requiring transfusion
 2 = Bleeding not requiring transfusion
 3 = Cardiopulmonary events (hypotension, hypoxia, arrhythmia,
 etc.)
 4 = Complications related to anesthesia
 5 = Bowel perforation
 6 = Post-polypectomy syndrome/excessive abdominal pain
 7 = Death
 8 = Other
99 = Unknown

EXPLANATION: Grantees may report the worst of up to two distinct serious complications occurring within 30 days of the test date and resulting in an emergency room visit, hospitalization or death. One complication should be reported in Item 9.07, and the other in Item 9.08.

If there were no complications reported by the client or clinician, report 0 (No complications reported) in both Items 9.07 and 9.08. If the client only experienced one complication, report that complication in Item 9.07 and then report 0 (No complications reported) in Item 9.08.

If Item 9.07 = 8 (Other), then Item 9.09 (Complications of endoscopy or DCBE - other specify) should be completed.

EXAMPLE: If the client experienced bleeding, but did not require a transfusion: 2

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **9.08: Complications (2) of endoscopy or DCBE requiring observation or treatment**

PURPOSE: To indicate a second complication that occurred due to a DCBE or endoscopy procedure.

LENGTH: 2

FIELD LOCATION: 439 - 440

TYPE: Numeric - right justify

SKIP PATTERN: If Item 6.x.01 (Test Performed) was 3 (Sigmoidoscopy), 4 (Colonoscopy), 5 (DCBE) or 7 (Other) then this field should be completed. Otherwise, leave blank.

CONTENTS: 0 = N/A – no 2nd complication reported
 1 = Bleeding requiring transfusion
 2 = Bleeding not requiring transfusion
 3 = Cardiopulmonary events (hypotension, hypoxia, arrhythmia,
 etc.)
 4 = Complications related to anesthesia
 5 = Bowel perforation
 6 = Post-polypectomy syndrome/excessive abdominal pain
 7 = Death
 8 = Other
99 = Unknown

EXPLANATION: Grantees may report the worst of up to two distinct serious complications occurring within 30 days of the test date and resulting in an emergency room visit, hospitalization or death. One complication should be reported in Item 9.07, and the other in Item 9.08.

If there were no complications reported by the client or clinician, report 0 (No complications reported) in both Items 9.07 and 9.08. If the client only experienced one complication, report that complication in Item 9.07 and then report 0 (No complications reported) in Item 9.08.

If Item 9.08 = 8 (Other), then Item 9.09 (Complications of endoscopy or DCBE - other specify) should be completed.

EXAMPLE: If the client experienced bleeding, but did not require a transfusion: 2

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **9.09: Complications of endoscopy or DCBE – Other specify**

PURPOSE: To specify the type of “other” complication reported in Item 9.07 or Item 9.08.

LENGTH: 40

FIELD LOCATION: 441 - 480

TYPE: Free text

SKIP PATTERN: If Item 9.07 or Item 9.08 = 8 (Other), then this field should be completed; otherwise, leave blank.

EXPLANATION: This field captures the type of “other” complication indicated in Item 9.07 and/or Item 9.08. Try to use this item appropriately. Reclaiming inappropriate “other” responses is time consuming and could potentially result in the loss of valuable data. Acceptable other complications would include infection (bacteremia or abscess) or allergic reaction to sedative.

This field should not be used to report a third complication. It is appropriate for each grantee to collect as much information as possible about all complications experienced; however, it is only necessary to report the two worst complications to the CDC.

EXAMPLE: If the client experienced an infection: Infection

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **9.10: CRCCP funds used for any screening/diagnostic test?**

PURPOSE: To indicate if CRCCP funds were used to pay for any of the screening or diagnostic tests reported in 6.x.01.

LENGTH: 1

FIELD LOCATION: 481

TYPE: Numeric

SKIP PATTERN: If at least one test was completed, then this field should be completed; otherwise, leave blank.

CONTENTS: 1 = Yes
2 = No
9 = Unknown

EXPLANATION: If the funding source for the screening or diagnostic test is documented, then a response of 1 (Yes) or 2 (No) should be reported. If the funding source cannot be determined, then a response of 3 (Unknown) should be reported.

EXAMPLE: If the client had an FOBT that was paid for with CRCCP funds: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

TEM NO / NAME: **10.1: Recurrent cancers**

PURPOSE: Indicate if the cancer reported in Item 9.02 (Final Diagnosis) is a new primary, a recurrent cancer, or a non-CRC primary cancer.

LENGTH: 1

FIELD LOCATION: 482

TYPE: Numeric

SKIP PATTERN: If Item 9.02 (Final Diagnosis) is 5 (Cancer), then this field should be completed; otherwise, leave blank.

CONTENTS: 1 = New CRC primary
2 = Recurrent CRC
3 = Non-CRC primary (metastasis from another organ)
9 = Unknown

EXPLANATION: If the cancer reported in Item 9.02 is a new primary colorectal cancer, report 1 (New CRC primary). If the cancer is a metastasis of a non-colorectal primary, then report it as 3 (Non-CRC primary).

An example of when 9 (Unknown) might be reported is if cells are so poorly differentiated that the organ of origin cannot be identified. This should occur rarely.

Grantees will need to work with their Cancer Registry to determine if a cancer is a new CRC primary, a non-CRC primary or a recurrent CRC cancer.

EXAMPLE: If the cancer found is a recurrent CRC cancer: 2

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **10.2:**  **Status of treatment**

PURPOSE: To specify the status of standard treatment for any cancer diagnosed.

LENGTH: 1

FIELD LOCATION: 483

TYPE: Numeric

SKIP PATTERN: If Item 9.02 (Final Diagnosis) = 5 (Cancer), then this field should be completed.

 If Item 9.02 = 4 (Adenomatous polyp with high grade dysplasia), then this field may be completed; however, Item 10.2 may not = 3 (Treatment not indicated due to polypectomy), 4 (Treatment not recommended) or 9 (Unknown).

Leave blank if Item 9.02 = 1(Normal/Negative), 2 (Hyperplastic polyps) or 3 (Adenomatous polyp, no high grade dysplasia).

CONTENTS: 1 = Treatment started and/or completed
2 = Treatment pending
3 = Treatment not indicated due to polypectomy
4 = Treatment not recommended
5 = Treatment refused
6 = Lost to follow-up
9 = Unknown

EXPLANATION: For the purpose of this program, the CDC requires the reporting of standard or conventional treatments. Non-standard or alternative treatments should not be reported as 1 (Treatment Started). In the event that the client chooses a form of non-standard or alternative treatment, this field should be coded as 5 (Treatment refused).

NOTE: Experimental drugs, such as those used in clinical trials, may be reported as 1 (Treatment started).

The fact that a client is referred for standard treatment is NOT sufficient confirmation that treatment has been started. A client should be classified as having started treatment only when the grantee has confirmed that a plan for standard treatment has been developed and actually started. The date when standard treatment began refers to the client’s actual start of therapy.

Endoscopy can often achieve screening and treatment simultaneously, by detecting and removing a polyp. A complete polypectomy would be considered both diagnostic and the only required treatment. In this case, the procedure should be reported in the Screening and Diagnostic Tests Performed section (Item 6.x.01), Treatment should be reported as 3 (Treatment not indicated due to polypectomy), and Item 10.3 (Date of Treatment) will be the day of the polypectomy. In this instance, Item 9.03 (Date of final diagnosis) and Item 10.3 (Date of treatment) would be the same.

 In the circumstance that surgical removal of a polyp or cancer (to complete a diagnosis) is complete, with no evidence of spreading, the surgery would also be considered both diagnostic and the only required treatment. In this case, the date of surgery should be reported in Item 8.2 (Date of Surgery), Treatment should be 3 (Treatment not indicated due to polypectomy), and Item 10.3 (Date of Treatment) will be the day of the surgery.

If any additional treatment beyond a polypectomy or surgery is required because of local or distant spread of a cancer (e.g. chemotherapy or radiation therapy), the Status of Treatment and Date of Treatment need to be determined by the start of the standard or conventional treatment beyond that of the polypectomy or surgery.

 Each grantee must have a policy in place to define how much time can elapse before the client is considered 5 (Treatment refused) or 6 (Lost to follow-up).

EXAMPLE: If client refused treatment: 5

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **10.3:**  **Date of treatment**

PURPOSE: To report the date treatment began.

LENGTH: 8

FIELD LOCATION: 484 - 491

TYPE: Date

SKIP PATTERN: If Item 10.2 (Status of treatment) = 2 (Treatment pending) or 9 (Unknown), this field must be blank; otherwise it must be completed.

If Item 10.2 (Status of treatment) = 1 (Treatment started and/or completed), 3 (Treatment not indicated due to polypectomy), 4 (Treatment not recommended), 5 (Treatment refused) or 6 (Lost to follow-up), then this item should be completed.

CONTENTS: An 8-digit date field of the form MMDDYYYY, where MM is the month of treatment from 01 to 12, DD is the day of treatment from 01 to 31, and YYYY is the year of treatment, including the century. If any part of the date is unknown, blank-fill only that part. For example, if the month and year of treatment are known, but the day is not, then blank-fill the day (e.g. 08 2010).

EXPLANATION: If Item 10.2 (Status of Treatment) is 1 (Started), then complete with the date the treatment began.

The fact that a client is referred for standard treatment is not sufficient confirmation that treatment has been started. A client should be classified as having started treatment only when the grantee has confirmed that a plan for standard treatment has been developed and actually started. The date when standard treatment began refers to the client’s actual start of therapy.

Endoscopy can often achieve screening and treatment simultaneously, by detecting and removing a polyp. A complete polypectomy would be considered both diagnostic and the only required treatment. In this case, the procedure should be reported in the Screening and Diagnostic Tests Performed section (6.x.01), Treatment should be reported as 3 (Treatment not indicated due to polypectomy), and Item 10.3 (Date of Treatment) will be the day of the polypectomy. In this instance, Item 9.03 (Date of final diagnosis) and Item 10.3 (Date of Treatment) would be the same.

In the circumstance that surgical removal of a polyp or cancer (to complete a diagnosis) is complete, with no evidence of spread, the surgery would also be considered both diagnostic and the only required treatment. In this case, the date of surgery should be reported in Item 8.2 (Date of Surgery), Treatment should be 3 (Treatment not indicated due to polypectomy), and Item 10.3 (Date of Treatment) will be the day of the surgery.

If any additional treatment beyond a polypectomy or surgery to complete diagnosis is required because of local or distant spread of a cancer (e.g. chemotherapy or radiation therapy), the Status of Treatment and Date of Treatment need to be determined by the start of the standard or conventional treatment beyond that of the polypectomy or surgery to complete diagnosis.

Each grantee must have a policy in place to define how much time can elapse before the client is considered 5 (Treatment refused) or 6 (Lost to follow-up).

Each grantee must have a policy in place to define how much time can elapse before the client is considered to be “Refused” or “Lost to follow-up”

EXAMPLE: Client began chemotherapy on December 15, 2010: 12152010

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **11.01: Registry linkage status**

PURPOSE: To indicate if the record for the client reported in Item 9.02 (Final Diagnosis) has been linked to the state/central cancer registry.

LENGTH: 1

FIELD LOCATION: 492

TYPE: Numeric

SKIP PATTERN: This field should only be completed if Item 9.02 (Final Diagnosis) was reported as 4 (Adenomatous Polyp with high grade dysplasia) or 5 (Cancer); otherwise, leave blank.

CONTENTS: 1 = Pending linkage
2 = Linked, matched
3 = Linked, not matched

EXPLANATION: At the time of each CCDE submission, this field should be updated to indicate if the record has been linked to the state/central cancer registry or not.

If your Program has not linked a record with the Cancer Registry at the time of the CCDE submission, report this item as 1 (Pending linkage).

If your Program has successfully matched a record with the Cancer Registry at the time of the CCDE submission, report this item as 2 (Linked, matched).

If during the linkage process a record in the CCDEs is NOT identified in the state/central cancer registry (based on matching algorithm guidelines developed by CDC using a combination of client identifiers such as name and date of birth), indicate 3 (Linked, not matched).

EXAMPLE: If the case is matched with a record in the state/central cancer registry: 2

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **11.02: Registry Date of Diagnosis**

PURPOSE: To report the date of diagnosis obtained from the state/central cancer registry.

LENGTH: 8

FIELD LOCATION: 493 - 500

TYPE: Date - MMDDYYYY format

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending linkage) or 3 (Linked, not matched).

CONTENTS: An 8-digit date item of the form MMDDYYYY, where MM (month) is the month of diagnosis from 01 to 12, DD (day) is the day of diagnosis from 01 to 31, and YYYY is the year of the diagnosis, including the century. If any part of the date is unknown, blank fill only that part. For example, if the month and year of diagnosis are known, but the day is not, then blank fill the day (e.g. 08 2010).

EXPLANATION: This item should indicate the date of diagnosis [NAACCR data item # 390] obtained from the state/central cancer registry.

Please note that Item 9.03 (the Date of Final Diagnosis) and Item 11.02 may differ in many instances.

EXAMPLE: If the Registry Date of Diagnosis is 08/28/2010: 08282010.

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **11.03: Registry Histologic Type**

PURPOSE: To report the histologic type obtained from the state/central cancer registry.

LENGTH: 4

FIELD LOCATION: 501 - 504

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending linkage) or 3 (Linked, not matched).

CONTENTS: Values for Item 11.03 (Registry Histologic Type) fall within the range of 8000 to 9989.

**NOTE:** See Chapter 3 (Registry Linkage) for a list of the most common [histology/behavior codes](#RL_1103) and their definitions as reported in the *Collaborative Staging Manual Coding Instructions.*

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked, matched), then report the Registry Histologic Type [NAACCR data item # 522] obtained from the state/central cancer registry database.

EXAMPLE: If the Registry Histologic Type is 8070: 8070.

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **11.04: Registry Behavior**

PURPOSE: To indicate the behavior code obtained from the state/central cancer registry.

LENGTH: 1

FIELD LOCATION: 505

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending linkage) or 3 (Linked, not matched).

CONTENTS: 0 = Benign
1 = Uncertain whether benign or malignant/Borderline malignancy
2 = Carcinoma, In Situ
3 = Malignant

**NOTE:** See Chapter 3 (Registry Linkage) for a list of the most common [histology/behavior codes](#RL_1104) and their definitions as reported in the *Collaborative Staging Manual Coding Instructions.*

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked, matched), then report the Registry Behavior type [NAACCR data item # 523] obtained from the state/central cancer registry database.

EXAMPLE: If the Registry Behavior indicates “Malignant”: 3

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **11.05: Registry primary site**

PURPOSE: To report the primary site obtained from the state/central cancer registry.

LENGTH: 4

FIELD LOCATION: 506 - 509

TYPE: Alphanumeric - left justify

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending linkage) or 3 (Linked, not matched).

CONTENTS: C000 through C999. The “C” must be included as part of the variable response.

Chapter 3 (Registry Linkage) contains documentation which provides a table of available [primary site codes](#RL_1105) as listed in the topography section of the *International Classification of Diseases for Oncology*, Third Edition (ICD-O-3).

EXPLANATION: If Item 11.1 (Registry linkage status) is reported as 2 (Linked, matched), the primary site [NAACCR data item #400] obtained from the cancer registry should be reported.

EXAMPLE: If the primary site is cecum: C180

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **11.06: Registry CS-derived SS2000**

PURPOSE: To report the derived summary stage obtained from the state/central cancer registry.

LENGTH: 1

FIELD LOCATION: 510

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending linkage) or 3 (Linked, not matched).

CONTENTS: 0 = In situ
1 = Localized
2 = Regional, direct extension only
3 = Regional, regional lymph nodes only
4 = Regional, extension and nodes
5 = Regional, NOS
7 = Distant
8 = Not applicable
9 = Unknown/unstaged

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked, matched), then report the collaborative stage (CS)-derived summary stage 2001 [NAACCR data item #3020] obtained from the cancer registry database. Please refer to the Web site [www.cancerstaging.org](http://www.cancerstaging.org) for general instructions provided to cancer registry sites on reporting this information.

Chapter 3 (Registry Linkage) has additional information for this item.

EXAMPLE: If the registry CS-derived stage is localized: 1

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **11.07: Registry CS-derived AJCC stage group**

PURPOSE: To report the CS-derived AJCC stage group as indicated by the state/central cancer registry.

LENGTH: 3

FIELD LOCATION: 511 – 513

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending linkage) or 3 (Linked, not matched).

CONTENTS: Valid values for CS-derived AJCC stage include: 000, 010, 020, 100, 110, 120, 130, 140, 121, 150, 160, 170, 151, 180, 190, 230, 240, 200, 210, 220, 300, 310, 320, 321, 322, 323, 330, 340, 350, 360, 370, 380, 390, 400, 410, 420, 430, 500, 510, 520, 530, 540, 541, 542, 550, 560, 570, 580, 590, 600, 610, 620, 630, 700, 710, 720, 721, 722, 730, 740, 888, 900, 999.

**NOTE:** See Chapter 3 (Registry Linkage) for a complete list of all [available codes](#RL_1107) and their definitions as reported in the *Collaborative Staging Manual Coding Instructions.*

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked, matched), then report the collaborative stage (CS)-derived AJCC stage [NAACCR data item #3000] obtained from the cancer registry database.

EXAMPLE: If polyp was diagnosed as a Stage II: 300

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **11.08: Registry CS extension**

PURPOSE: To indicate the extension of disease, as reported by the state/central cancer registry.

LENGTH: 3

FIELD LOCATION: 514 – 516

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending linkage) or 3 (Linked, not matched).

CONTENTS: Valid values for CS extension include: 000, 050, 100, 110, 120, 130, 140, 150, 160, 170, 200, 300, 400, 410, 420, 450, 460, 490, 500, 550, 560, 570, 600, 650, 660, 700, 750, 800, 850, 900, 950, 999.

**NOTE:** See Chapter 3 (Registry Linkage) for a complete list of all [available codes](#RL_1108) and their definitions as reported in the *Collaborative Staging Manual Coding Instructions.*

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked, matched), then report the collaborative stage (CS)-derived extension [NAACCR data item #2810] obtained from the cancer registry database.

EXAMPLE: If the CS reported extension for Colon is “Localized, NOS”: 300

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **11.09: Registry CS lymph nodes**

PURPOSE: To indicate the lymph node involvement, as reported by the state/central cancer registry.

LENGTH: 3

FIELD LOCATION: 517 – 519

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending linkage) or 3 (Linked, not matched).

CONTENTS: Valid values for CS lymph nodes are 000, 050, 100, 200, 300, 400, 410, 420, 450, 460, 470, 800, 999.

**NOTE:** See Chapter 3 (Registry Linkage) for a complete list of all [available codes](#RL_1109) and their definitions as reported in the *Collaborative Staging Manual Coding Instructions.*

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked, matched), then report the collaborative stage (CS) lymph node involvement [NAACCR data item #2830] obtained from the cancer registry database.

EXAMPLE: If the primary site is colon, and the lymph nodes involvement reported is “Regional lymph node(s) for ascending colon: 200

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **11.10: Registry CS mets at diagnosis**

PURPOSE: To indicate any distant metastases at the time of diagnosis, as reported by the state/central cancer registry.

LENGTH: 2

FIELD LOCATION: 520 – 521

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending linkage) or 3 (Linked, not matched).

CONTENTS: 00, 05, 08, 15, 20, 22, 25, 27, 30, 35, 38, 45, 60, 99.

10, 11, 12, 40 and 50 are valid but obsolete codes and should be used infrequently.

**NOTE:** See Chapter 3 (Registry Linkage) for a complete list of all [available codes](#RL_1110) and their definitions as reported in the *Collaborative Staging Manual Coding Instructions.*

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked, matched), then report the CS mets at diagnosis [NAACCR data item #2850] obtained from the cancer registry database.

EXAMPLE: If the mets at diagnosis are reported as “None”: 00

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **11.11: Registry Collaborative Stage (CS) – Tumor Size**

PURPOSE: To report the tumor size as indicated by the state/central cancer registry.

LENGTH: 3

FIELD LOCATION: 522 – 524

TYPE: Numeric

SKIP PATTERN: Leave blank if Item 11.01 (Registry linkage status) = 1 (Pending linkage) or 3 (Linked, not matched).

CONTENTS: 001-988 Exact size in millimeters
989 = ≥ 989 millimeters
990 = Microscopic focus or foci only; no size of focus is given
991 = Described as less than 1 cm
992 = Described as between 1 cm and 2 cm
993 = Described as between 2 cm and 3 cm
994 = Described as between 3 cm and 4 cm
995 = Described as between 4 cm and 5 cm
998 = Familial/multiple polyposis
999 = Unknown; size not stated

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linked, matched), then report the Collaborative Stage (CS) Tumor Size [NAACCR data item # 2800] obtained from the state/central cancer registry database.

Not all cancer registries collect this information. If this field is blank in the Cancer Registry, report 999 (Unknown).

EXAMPLE: If CS-Tumor Size was described as between 3 cm and 4 cm: 994

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

ITEM NO / NAME: **12.1:**  **CCDE version**

PURPOSE: To report the CCDE version that the current record was collected in.

LENGTH: 3

FIELD LOCATION: 525 – 527

TYPE: Numeric

SKIP PATTERN: This field should always be completed.

CONTENTS: 100 = All data currently being collected/reported.

EXPLANATION: As the program begins to evaluate data collected, some variables may be dropped, new variables may be added, or additional options may be added to variable responses. As these changes occur, the CCDE version number will change.

EXAMPLE: Clinical data for a client was collected in March 2010: 100.

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| CCDE version | Date of revision | Type of revision |
| 1.00 | 12/02/2009 | Add new |

**CHAPTER 3**

**Registry Linkage**

Included in this chapter are tables from the *SEER Program Coding and Staging Manual 2007* ([http://seer.cancer.gov](http://seer.cancer.gov/tools/codingmanuals/)); and the *Collaborative Staging Manual and Coding Instructions, version 2.0,* jointly published by the American Joint Committee on Cancer (AJCC) and the U.S. Department of Health and Human Services (DHHS) (<http://www.cancerstaging.org> ).

These cancer staging manuals provide detailed descriptions for the following items in the CCDEs. These tables should be referenced in order to ensure accurate reporting of these variables and their values:

* CCDE Item 11.03: Registry Histologic type
* CCDE Item 11.04: Registry behavior
* CCDE Item 11.05: Registry primary site
* CCDE Item 11.06: Registry CS-derived SS2000
* CCDE Item 11.07: Registry CS-derived AJCC stage group
* CCDE Item 11.08: Registry CS extension
* CCDE Item 11.09: Registry CS lymph nodes
* CCDE Item 11.10: Registry CS mets at diagnosis
* CCDE Item 11.11: Registry CS tumor size

**CCDE Item 11.03: Registry Histologic Type and CCDE Item 11.04 Registry Behavior**

Registry Histologic Type [NAACCR data item #522] and Behavior [NAACCR data item #523] are often reported together. For example, ‘Adenocarcinoma in situ’ may be reported as ‘8140/2’, where ‘8140’ is the Histologic type, and ‘2’ is the behavior. For the purposes of this data user’s manual, we will provide the International Classification of Disease (ICD) Histology codes (ICD-0-3) that are most commonly associated with colorectal cancer. **If Programs receive a Histology/Behavior combination that is not listed below, they should verify the value with their State Central Cancer Registry.** The Histology table will include the Histology and Behavior codes together in order to provide a more detailed description of each value.

**11.04 Registry Behavior (alone)**

|  |  |
| --- | --- |
| **Value** | **Description** |
| 0 | Benign |
| 1 | Uncertain whether benign or malignant/Borderline malignancy |
| 2 | Carcinoma In Situ |
| 3 | Malignant |

| **Histology Description** | **Histology** | **Histology/****Behavior** | **Histology/Behavior Description** |
| --- | --- | --- | --- |
| NEOPLASM | 800 | 8000/3 | Neoplasm, malignant |
|  |  | 8001/3 | Tumor cells, malignant |
|  |  | 8002/3 | Malignant tumor, small cell type |
|  |  | 8003/3 | Malignant tumor, giant cell type |
|  |  | 8004/3 | Malignant tumor, spindle cell type |
|  |  | 8005/3 | Malignant tumor, clear cell type |
| CARCINOMA, NOS | 801 | 8010/2 | Carcinoma in situ, NOS |
|  |  | 8010/3 | Carcinoma, NOS |
|  |  | 8011/3 | Epithelioma, malignant |
|  |  | 8012/3 | Large cell carcinoma, NOS |
|  |  | 8013/3 | Large cell neuroendocrine carcinoma |
|  |  | 8014/3 | Large cell carcinoma with rhabdoid phenotype |
|  |  | 8015/3 | Glassy cell carcinoma |
| CARCINOMA, UNDIFF., NOS | 802 | 8020/3 | Carcinoma, undifferentiated type, NOS |
|  |  | 8021/3 | Carcinoma, anaplastic type, NOS |
|  |  | 8022/3 | Pleomorphic carcinoma |
| GIANT & SPINDLE CELL CARCINOMA | 803 | 8030/3 | Giant cell and spindle cell carcinoma |
|  |  | 8031/3 | Giant cell carcinoma |
|  |  | 8032/3 | Spindle cell carcinoma |
|  |  | 8033/3 | Pseudosarcomatous carcinoma |
|  |  | 8034/3 | Polygonal cell carcinoma |
|  |  | 8035/3 | Carcinoma with osteoclast-like giant cells |
| SMALL CELL CARCINOMA, NOS | 804 | 8041/3 | Small cell carcinoma, NOS |
|  |  | 8043/3 | Small cell carcinoma, fusiform cell |
|  |  |  |  |
| PAPILLARY CARCINOMA, NOS | 805 | 8050/2 | Papillary carcinoma in situ |
|  |  | 8050/3 | Papillary carcinoma, NOS |
|  |  | 8051/3 | Verrucous carcinoma, NOS |
|  |  | 8052/2 | Papillary squamous cell carcinoma, non-invasive |
|  |  | 8052/3 | Papillary squamous cell carcinoma |
| SQUAMOUS CELL CARCINOMA, NOS | 807 | 8070/2 | Squamous cell carcinoma in situ, NOS |
|  |  | 8070/3 | Squamous cell carcinoma, NOS |
|  |  | 8071/3 | Sq. cell carcinoma, keratinizing, NOS |
|  |  | 8072/3 | Sq. cell carcinoma, lg. cell, non-ker. |
|  |  | 8073/3 | Sq. cell carcinoma, sm. cell, non-ker. |
|  |  | 8074/3 | Sq. cell carcinoma, spindle cell |
|  |  | 8075/3 | Squamous cell carcinoma, adenoid |
|  |  | 8076/2 | Sq. cell carc. in situ with question. stromal invas. |
|  |  | 8076/3 | Sq. cell carcinoma, micro-invasive |
|  |  | 8078/3 | Squamous cell carcinoma with horn formation |
| TRANSITIONAL CELL CARCINOMA, NOS | 812 | 8120/2 | Transitional cell carcinoma in situ |
|  |  | 8120/3 | Transitional cell carcinoma, NOS |
|  |  | 8121/3 | Schneiderian carcinoma |
|  |  | 8122/3 | Trans. cell carcinoma, spindle cell |
|  |  | 8123/3 | Basaloid carcinoma |
|  |  | 8124/3 | Cloacogenic carcinoma |
| ADENOCARCINOMA, NOS | 814 | 8140/2 | Adenocarcinoma in situ |
|  |  | 8140/3 | Adenocarcinoma, NOS |
|  |  | 8141/3 | Scirrhous adenocarcinoma |
|  |  |  |  |
| ADENOCARCINOMA, NOS (cont’d) | 814 | 8143/3 | Superficial spreading adenocarcinoma |
|  |  | 8145/3 | Carcinoma, diffuse type |
|  |  | 8147/3 | Basal cell adenocarcinoma |
| ADENOCA. IN ADENOMA. POLYP | 821 | 8210/2 | Adenocarcinoma in situ in adenomatous polyp |
|  |  | 8210/3 | Adenocarcinoma in adenomatous polyp |
|  |  | 8211/3 | Tubular adenocarcinoma |
| ADENOCA IN FAMIL POLYP COLI | 822 | 8220/2 | Adenocarcinoma in situ in familial polyp. coli |
|  |  | 8220/3 | Adenocarcinoma in adenoma. polyposis coli |
|  |  | 8221/2 | Adenocarc. in situ in mult. adenomatous polyps |
|  |  | 8221/3 | Adenocarcinoma in mult. adenomatous polyps |
| SOLID CARCINOMA, NOS | 823 | 8230/2 | Duct carcinoma in situ, solid type |
|  |  | 8230/3 | Solid carcinoma, NOS |
|  |  | 8231/3 | Carcinoma simplex |
| CARCINOID TUMOR, MALIGNANT | 824 | 8240/3 | Carcinoid tumor, malignant |
|  |  | 8241/3 | Enterochromaffin cell carcinoid |
|  |  | 8242/3 | Enterochromaffin-like cell tumor, malignant |
|  |  | 8243/3 | Goblet cell carcinoid |
|  |  | 8244/3 | Composite carcinoid |
|  |  | 8245/3 | Adenocarcinoid tumor |
|  |  | 8246/3 | Neuroendocrine carcinoma |
|  |  | 8249/3 | Atypical carcinoid tumor |
| BRONCHIOLO-ALVEOLAR ADENOCA. | 825 | 8255/3 | Adenocarcinoma with mixed subtypes |
| PAPILLARY ADENOCARCINOMA, NOS | 826 | 8260/3 | Papillary adenocarcinoma, NOS |
|  |  | 8261/2 | Adenocarcinoma in situ in villous adenoma |
|  |  | 8261/3 | Adenocarcinoma in villous adenoma |
|  |  | 8262/3 | Villous adenocarcinoma |
| PAPILLARY ADENOCARCINOMA, NOS | 826 | 8263/2 | Adenocarcinoma in situ in tubulovillous adenoma |
|  |  | 8263/3 | Adenocarcinoma in tubulovillous adenoma |
| MUCOEPIDERMOID CARCINOMA | 843 | 8430/3 | Mucoepidermoid carcinoma |
| CYSTADENOCARCINOMA, NOS | 844 | 8440/3 | Cystadenocarcinoma, NOS |
| MUCINOUS ADENOCARCINOMA | 848 | 8480/3 | Mucinous adenocarcinoma |
|  |  | 8481/3 | Mucin-producing adenocarcinoma |
| SIGNET RING CELL CARCINOMA | 849 | 8490/3 | Signet ring cell carcinoma |
| MEDULLARY CARCINOMA, NOS | 851 | 8510/3 | Medullary carcinoma, NOS |
| ACINAR CELL CARCINOMA | 855 | 8550/3 | Acinar cell carcinoma |
|  |  | 8551/3 | Acinar cell cystadenocarcinoma |
| ADENOSQUAMOUS CARCINOMA | 856 | 8560/3 | Adenosquamous carcinoma |
|  |  | 8562/3 | Epithelial-myoepithelial carcinoma |
| ADENOCA. WITH METAPLASIA | 857 | 8570/3 | Adenocarcinoma with squamous metaplasia |
|  |  | 8571/3 | Adenocarcinoma w cartilag. & oss. metaplas. |
|  |  | 8572/3 | Adenocarcinoma with spindle cell mataplasia |
|  |  | 8573/3 | Adenocarcinoma with apocrine metaplasia |
|  |  | 8574/3 | Adenocarcinoma with neuroendocrine differen. |
|  |  | 8575/3 | Metaplastic carcinoma, NOS |
|  |  | 8576/3 | Hepatoid adenocarcinoma |
| NEVI & MELANOMAS | 872 | 8720/2 | Melanoma in situ |
|  |  | 8720/3 | Malignant melanoma, NOS |
|  |  | 8721/3 | Nodular melanoma |
|  |  | 8722/3 | Balloon cell melanoma |
|  |  | 8723/3 | Malignant melanoma, regressing |
| AMELANOTIC MELANOMA | 873 | 8730/3 | Amelanotic melanoma |
|  |  |  |  |
| MAL. MEL. IN JUNCT. NEVUS | 874 | 8743/3 | Superficial spreading melanoma |
|  |  | 8745/3 | Desmoplastic melanoma, malignant |
|  |  | 8746/3 | Mucosal lentiginous melanoma |
| MAL. MELAN. IN GIANT PIGMT. NEVUS | 876 | 8761/3 | Mal. melanoma in giant pigmented nevus |
| EPITHELIOID CELL MELANOMA | 877 | 8770/3 | Mixed epithel. & spindle cell melanoma |
|  |  | 8771/3 | Epithelioid cell melanoma |
|  |  | 8772/3 | Spindle cell melanoma, NOS |
| SARCOMA, NOS | 880 | 8800/3 | Sarcoma, NOS |
|  |  | 8801/3 | Spindle cell sarcoma |
|  |  | 8802/3 | Giant cell sarcoma |
|  |  | 8803/3 | Small cell sarcoma |
|  |  | 8804/3 | Epithelioid sarcoma |
|  |  | 8805/3 | Undifferentiated sarcoma |
|  |  | 8806/3 | Desmoplastic small round cell tumor |
| FIBROMATOUS NEOPLASMS | 881 | 8810/3 | Fibrosarcoma, NOS |
|  |  | 8811/3 | Fibromyxosarcoma |
|  |  | 8813/3 | Fascial fibrosarcoma |
|  |  | 8814/3 | Infantile fibrosarcoma |
|  |  | 8815/3 | Solitary fibrous tumor, malignant |
| LIPOSARCOMA NEOPLASMS | 885 | 8850/3 | Liposarcoma, NOS |
|  |  | 8851/3 | Liposarcoma, well differentiated |
|  |  | 8852/3 | Myxoid liposarcoma |
|  |  | 8853/3 | Round cell liposarcoma |
|  |  | 8854/3 | Pleomorphic liposarcoma |
|  |  |  |  |
| LIPOSARCOMA NEOPLASMS (cont’d) | 885 | 8855/3 | Mixed type liposarcoma |
|  |  | 8857/3 | Fibroblastic liposarcoma |
|  |  | 8858/3 | Dedifferentiated liposarcoma |
| MYOMATOUS NEOPLASMS | 889 | 8890/3 | Leiomyosarcoma, NOS |
|  |  | 8891/3 | Epithelioid leiomyosarcoma |
|  |  | 8894/3 | Angiomyosarcoma |
|  |  | 8895/3 | Myosarcoma |
|  |  | 8896/3 | Myxoid leiomyosarcoma |
| STROMAL SARCOMA | 893 | 8934/3 | Carcinofibroma |
|  |  | 8935/3 | Stromal sarcoma, NOS |
|  |  | 8936/3 | Gastrointestinal stromal sarcoma |
| CARCINOSARCOMA, NOS | 898 | 8980/3 | Carcinosarcoma, NOS |
|  |  | 8981/3 | Carcinosarcoma, embryonal type |
|  |  | 8982/3 | Malignant myoepithelioma |
| MALIGNANT LYMPHOMA, NOS | 959 | 9590/3 | Malignant lymphoma, NOS |
|  |  | 9591/3 | Malignant lymphoma, non-Hodgkin |
|  |  | 9596/3 | Composite Hodgkin and non-Hodgkin lymphoma |
| HODGKIN LYMPHOMA | 965 | 9650/3 | Hodgkin lymphoma, NOS |
|  |  | 9651/3 | Hodgkin lymphoma, lymphocyte-rich |
|  |  | 9652/3 | Hodgkin lymphoma, mixed cellularity, NOS |
|  |  | 9653/3 | Hodgkin lymphoma, lymphocytic deplet., NOS |
|  |  | 9654/3 | Hodgkin lymphoma, lymphocytic deplet., diffuse fibrosis |
|  |  | 9655/3 | Hodgkin lymphoma, lymphocyt. deplet., reticular |
|  |  | 9659/3 | Hodgkin lymph., nodular lymphocyte predom. |
|  |  |  |  |
| HODGKIN LYMPHOMA, NOD. SCLER. | 966 | 9661/3 | Hodgkin granuloma [obs] |
|  |  | 9662/3 | Hodgkin sarcoma [obs] |
|  |  | 9663/3 | Hodgkin lymphoma, nodular sclerosis, NOS |
|  |  | 9664/3 | Hodgkin lymphoma, nod. scler., cellular phase |
|  |  | 9665/3 | Hodgkin lymphoma, nod. scler., grade 1 |
|  |  | 9667/3 | Hodgkin lymphoma, nod. scler., grade 2 |
| ML, SMALL B-CELL LYMPHOCYTIC | 967 | 9670/3 | ML, small B lymphocytic, NOS |
|  |  | 9671/3 | ML, lymphoplasmacytic |
|  |  | 9673/3 | Mantle cell lymphoma |
|  |  | 9675/3 | ML, mixed sm. and lg. cell, diffuse |
| ML, LARGE B-CELL, DIFFUSE | 968 | 9680/3 | ML, large B-cell, diffuse |
|  |  | 9684/3 | ML, large B-cell, diffuse, immunoblastic, NOS |
|  |  | 9687/3 | Burkitt lymphoma, NOS |
|  |  | 9688/3 | T-cell histiocyte rich large B-cell lymphoma |
| FOLLIC. & MARGINAL LYMPH, NOS | 969 | 9690/3 | Follicular lymphoma, NOS |
|  |  | 9691/3 | Follicular lymphoma, grade 2 |
|  |  | 9695/3 | Follicular lymphoma, grade 1 |
|  |  | 9698/3 | Follicular lymphoma, grade 3 |
|  |  | 9699/3 | Marginal zone B-cell lymphoma, NOS |
| T-CELL LYMPHOMAS | 970 | 9701/3 | Sezary syndrome |
|  |  | 9702/3 | Mature T-cell lymphoma, NOS |
|  |  | 9705/3 | Angioimmunoblastic T-cell lymphoma |
| OTHER SPEC. NON-HODGKIN LYMPHOMA | 971 | 9712/3 | Intravascular large B-cell lymphoma |
|  |  | 9714/3 | Anaplastic large cell lymphoma, T-cell and Null cell type |
|  |  | 9717/3 | Intestinal T-cell lymphoma |
| OTHER SPEC. NON-HODGKIN LYMPHOMA | 971 | 9719/3 | NK/T-cell lymphoma, nasal and nasal-type |
| PRECURS. CELL LYMPHOBLASTIC LYMPH. | 972 | 9724/3 | SystemicEBV pos. T-cell lymphoproliferative disease of childhood |
|  |  | 9727/3 | Precursor cell lymphoblastic lymphoma, NOS |
|  |  | 9728/3 | Precursor B-cell lymphoblastic lymphoma |
|  |  | 9729/3 | Precursor T-cell lymphoblastic lymphoma |
| PLASMA CELL TUMORS | 973 | 9731/3 | Plasmacytoma, NOS |
|  |  | 9734/3 | Plasmacytoma, extramedullary |
|  |  | 9735/3 | Plasmablastic lymphoma |
|  |  | 9737/3 | ALK positive large B-cell lymphoma |
|  |  | 9738/3 | Lrg B-cell lymphoma in HHV8-assoc. multicentric Castleman DZ |
| MAST CELL TUMORS | 974 | 9740/3 | Mast cell sarcoma |
|  |  | 9741/3 | Malignant mastocytosis |
| NEOPLASMS OF HISTIOCYTES AND ACCESSORY LYMPHOID CELLS | 975 | 9750/3 | Malignant histiocytosis |
|  |  | 9751/3 | Langerhans cell histiocytosis, NOS |
|  |  | 9754/3 | Langerhans cell histiocytosis, disseminated |
|  |  | 9755/3 | Histiocytic sarcoma |
|  |  | 9756/3 | Langerhans cell sarcoma |
| NEOPLASMS OF HISTIOCYTES AND ACCESSORY LYMPHOID CELLS (cont’d) |  | 9757/3 | Interdigitating dendritic cell sarcoma |
|  |  | 9758/3 | Follicular dendritic cell sarcoma |
|  |  | 9759/3 | Fibroblastic reticular cell tumor |
| PRECURSOR LYMPHOID NEOPLASMS | 981 | 9811/3 | B lymphoblastic leukemia/lymphoma, NOS |
|  |  | 9812/3 | Leukemia/lymphoma with t(9;22)(q34;q11.2);BCR-ABL1 |
|  |  | 9813/3 | Leukemia/lymphoma with t(v;11q23);MLL rearranged |
| PRECURSOR LYMPHOID NEOPLASMS | 981 | 9814/3 | Leukemia/lymphoma with t(12;21)(p13;q22);TEL-AML1(ETV6-RUNX1) |
|  |  | 9815/3 | B lymphoblastic leukemia/lymphoma with hyperdiploidy |
|  |  | 9816/3 | Leukemia/lymphoma with hypodiploidy (hypodiploid ALL) |
|  |  | 9817/3 | B lymphblastic leukemia/lymphoma with t(5;14)(q31;q32);IL3-IGH |
|  |  | 9818/3 | Leukemia/lymphoma with t(1;19)(q23;p13.3); E2A PBX1 (TCF3 PBX1) |
| PROLYMPH/PRECURS LEUKEMIA | 983 | 9831/3 | T-cell large granular lymphocytic leukemia |
|  |  | 9837/3 | T lymphoblastic leukemia/lymphoma |
| CHRONIC MYELOPROLIFERATIVE DIS. | 996 | 9965/3 | Myeloid and lymphoid neoplasms with PDGFRB rearrangement |
|  |  | 9967/3 | Myeloid and lymphoid neoplasm with FGFR1 abnormalities |
| MYELOPLASTIC/MYELOPROLIF. NEOPLASMS | 997 | 9971/3 | Polymorphic PTLD |
|  |  | 9975/3 | Myelodysplastic/Myeloproliferative neoplasm, unclassifiable |

**CCDE Item 11.05: Registry primary site**

Primary site [NAACCR data item #400] obtained from the central cancer registry database. See the SEER Program Coding and Staging Manual at <http://seer.cancer.gov>.

C000 = External upper lip

C001 = External lower lip

C002 = External lip, NOS

C003 = Mucosa of upper lip

C004 = Mucosa of lower lip

C005 = Mucosa of lip, NOS

C006 = Commissure of lip

C008 = Overlapping lesion of lip

C009 = Lip, NOS

C019 = Base of tongue, NOS

C020 = Dorsal surface of tongue, NOS

C021 = Border of tongue

C022 = Ventral surface of tongue, NOS

C023 = Anterior 2/3 of tongue, NOS

C024 = Lingual tonsil

C028 = Overlapping lesion of tongue

C029 = Tongue, NOS

C030 = Upper gum

C031 = Lower gum

C039 = Gum, NOS

C040 = Anterior floor of mouth

C041 = Lateral floor of mouth

C048 = Overlapping of floor of mouth

C049 = Floor of mouth, NOS

C050 = Hard palate

C051 = Soft palate, NOS

C052 = Uvula

C058 = Overlapping lesion of palate

C059 = Palate, NOS

C060 = Cheek mucosa

C061 = Vestibule of mouth

C062 = Retromolar area

C068 = Overlapping of other mouth

C069 = Mouth, NOS

C079 = Parotid gland

C080 = Submandibular gland

C081 = Sublingual gland

C088 = Overlapping maj salivary glands

C089 = Major salivary gland, NOS

C090 = Tonsillar fossa

C091 = Tonsillar pillar

C098 = Overlapping lesion of tonsil

C099 = Tonsil, NOS

C100 = Vallecula

C101 = Anterior surface of epiglottis

C102 = Lateral wall of oropharynx

C103 = Posterior wall of oropharynx

C104 = Branchial cleft

C108 = Overlapping of oropharynx

C109 = Oropharynx, NOS

C110 = Superior wall of nasopharynx

C111 = Posterior wall of nasopharynx

C112 = Lateral wall of nasopharynx

C113 = Anterior wall of nasopharynx

C118 = Overlapping of nasopharynx

C119 = Nasopharynx, NOS

C129 = Pyriform sinus

C130 = Postcricoid region

C131 = Aryepiglottic fold, hypophar.

C132 = Posterior wall of hypopharynx

C138 = Overlapping of hypopharynx

C139 = Hypopharynx, NOS

C140 = Pharynx, NOS

C142 = Waldeyer's ring

C148 = Overlap of pharynx, etc.

C150 = Cervical esophagus

C151 = Thoracic esophagus

C152 = Abdominal esophagus

C153 = Upper third of esophagus

C154 = Middle third of esophagus

C155 = Lower third of esophagus

C158 = Overlapping lesion of esophagus

C159 = Esophagus, NOS

C160 = Cardia, NOS

C161 = Fundus of stomach

C162 = Body of stomach

C163 = Gastric antrum

C164 = Pylorus

C165 = Lesser curvature stomach NOS

C166 = Greater curvature stomach NOS

C168 = Overlapping lesion of stomach

C169 = Stomach, NOS

C170 = Duodenum

C171 = Jejunum

C172 = Ileum

C173 = Meckel's diverticulum

C178 = Overlapping of small intestine

C179 = Small intestine, NOS

C180 = Cecum

C181 = Appendix

C182 = Ascending colon

C183 = Hepatic flexure of colon

C184 = Transverse colon

C185 = Splenic flexure of colon

C186 = Descending colon

C187 = Sigmoid colon

C188 = Overlapping of colon

C189 = Colon, NOS

C199 = Rectosigmoid junction

C209 = Rectum, NOS

C210 = Anus, NOS

C211 = Anal canal

C212 = Cloacogenic zone

C218 = Overlap of rectum, anus, etc.

C220 = Liver

C221 = Intrahepatic bile duct

C239 = Gallbladder

C240 = Extrahepatic bile duct

C241 = Ampulla of Vater

C248 = Overlapping of biliary tract

C249 = Biliary tract, NOS

C250 = Head of pancreas

C251 = Body of pancreas

C252 = Tail of pancreas

C253 = Pancreatic duct

C254 = Islets of Langerhans

C257 = Other spec pancreas

C258 = Overlapping of pancreas

C259 = Pancreas, NOS

C260 = Intestinal tract, NOS

C268 = Overlapping of digestive system

C269 = Gastrointestinal tract, NOS

C300 = Nasal cavity

C301 = Middle ear

C310 = Maxillary sinus

C311 = Ethmoid sinus

C312 = Frontal sinus

C313 = Sphenoid sinus

C318 = Overlap of accessory sinuses

C319 = Accessory sinus, NOS

C320 = Glottis

C321 = Supraglottis

C322 = Subglottis

C323 = Laryngeal cartilage

C328 = Overlapping of larynx

C329 = Larynx, NOS

C339 = Trachea

C340 = Main bronchus

C341 = Upper lobe, lung

C342 = Middle lobe, lung

C343 = Lower lobe, lung

C348 = Overlapping of lung

C349 = Lung, NOS

C379 = Thymus

C380 = Heart

C381 = Anterior mediastinum

C382 = Posterior mediastinum

C383 = Mediastinum, NOS

C384 = Pleura, NOS

C388 = Ovr. heart, mediastinum, pleura

C390 = Upper respiratory tract, NOS

C398 = Overlap of respiratory system

C399 = Ill-defined sites of resp sys

C400 = Long bones: upper limb, scapula

C401 = Short bones: upper limb

C402 = Long bones: lower limb

C403 = Short bones: lower limb

C408 = Overlap of bones, etc. of limbs

C409 = Bone of limb, NOS

C410 = Bones of skull and face

C411 = Mandible

C412 = Vertebral column

C413 = Rib, Sternum, Clavicle

C414 = Pelvic bones, Sacrum, Coccyx

C418 = Overlap bones, etc.

C419 = Bone, NOS

C420 = Blood

C421 = Bone marrow

C422 = Spleen

C423 = Reticuloendothelial system, NOS

C424 = Hematopoietic system, NOS

C440 = Skin of lip, NOS

C441 = Eyelid

C442 = External ear

C443 = Skin other/unspec parts of face

C444 = Skin of scalp and neck

C445 = Skin of trunk

C446 = Skin of upper limb and shoulder

C447 = Skin of lower limb and hip

C448 = Overlapping of skin

C449 = Skin, NOS

C470 = Periph nerves: head, face, neck

C471 = Peri nerves: upr limb, shoulder

C472 = Periph nerves: lower limb, hip

C473 = Periph nerves: thorax

C474 = Periph nerves: abdomen

C475 = Periph nerves: pelvis

C476 = Periph nerves: trunk, NOS

C478 = Overlap of peripheral nerves

C479 = Autonomic nervous system, NOS

C480 = Retroperitoneum

C481 = Specified parts of peritoneum

C482 = Peritoneum, NOS

C488 = Overlap retroper & peritoneum

C490 = Conn tissues: head, face, neck

C491 = Conn tissues: upr limb, shoulder

C492 = Conn tissues: lower limb, hip

C493 = Conn tissues: thorax

C494 = Conn tissues: abdomen

C495 = Conn tissues: pelvis

C496 = Conn tissues: trunk, NOS

C498 = Overlapping conn tissues

C499 = Conn tissues, NOS

C500 = Nipple

C501 = Central portion of breast

C502 = Upper-inner quadrant of breast

C503 = Lower-inner quadrant of breast

C504 = Upper-outer quadrant of breast

C505 = Lower-outer quadrant of breast

C506 = Axillary tail of breast

C508 = Overlapping of breast

C509 = Breast, NOS

C510 = Labium majus

C511 = Labium minus

C512 = Clitoris

C518 = Overlapping of vulva

C519 = Vulva, NOS

C529 = Vagina, NOS

C530 = Endocervix

C531 = Exocervix

C538 = Overlapping of cervix uteri

C539 = Cervix uteri

C540 = Isthmus uteri

C541 = Endometrium

C542 = Myometrium

C543 = Fundus uteri

C548 = Overlapping of corpus uteri

C549 = Corpus uteri

C559 = Uterus, NOS

C569 = Ovary

C570 = Fallopian tube

C571 = Broad ligament

C572 = Round ligament

C573 = Parametrium

C574 = Uterine adnexa

C577 = Other spec fem genital organs

C578 = Overlap of fem genital organs

C579 = Female genital tract, NOS

C589 = Placenta

C600 = Prepuce

C601 = Glans penis

C602 = Body of penis

C608 = Overlapping of penis

C609 = Penis, NOS

C619 = Prostate gland

C620 = Undescended testis

C621 = Descended testis

C629 = Testis, NOS

C630 = Epididymis

C631 = Spermatic cord

C632 = Scrotum, NOS

C637 = Other spec male genital organs

C638 = Overlap male genital organs

C639 = Male genital organs, NOS

C649 = Kidney, NOS

C659 = Renal pelvis

C669 = Ureter

C670 = Trigone of bladder

C671 = Dome of bladder

C672 = Lateral wall of bladder

C673 = Anterior wall of bladder

C674 = Posterior wall of bladder

C675 = Bladder neck

C676 = Ureteric orifice

C677 = Urachus

C678 = Overlapping of bladder

C679 = Bladder, NOS

C680 = Urethra

C681 = Paraurethral gland

C688 = Overlapping of urinary organs

C689 = Urinary system, NOS

C690 = Conjunctiva

C691 = Cornea, NOS

C692 = Retina

C693 = Choroid

C694 = Ciliary body

C695 = Lacrimal gland

C696 = Orbit, NOS

C698 = Overlapping of eye and adnexa

C699 = Eye, NOS

C700 = Cerebral meninges

C701 = Spinal meninges

C709 = Meninges, NOS

C710 = Cerebrum

C711 = Frontal lobe

C712 = Temporal lobe

C713 = Parietal lobe

C714 = Occipital lobe

C715 = Ventricle, NOS

C716 = Cerebellum, NOS

C717 = Brain stem

C718 = Overlapping of brain

C719 = Brain, NOS

C720 = Spinal cord

C721 = Cauda equina

C722 = Olfactory nerve

C723 = Optic nerve

C724 = Acoustic nerve

C725 = Cranial nerve, NOS

C728 = Overlap of brain & CNS

C729 = Nervous system, NOS

C739 = Thyroid gland

C740 = Cortex of adrenal gland

C741 = Medulla of adrenal gland

C749 = Adrenal gland, NOS

C750 = Parathyroid gland

C751 = Pituitary gland

C752 = Craniopharyngeal duct

C753 = Pineal gland

C754 = Carotid body

C755 = Aortic body & other paraganglia

C758 = Overlapping of endocrine glands

C759 = Endocrine gland, NOS

C760 = Head, face or neck, NOS

C761 = Thorax, NOS

C762 = Abdomen, NOS

C763 = Pelvis, NOS

C764 = Upper limb, NOS

C765 = Lower limb, NOS

C767 = Other ill-defined sites

C768 = Overlap of ill-defined sites

C770 = Lymph nodes: head, face & neck

C771 = Intrathoracic lymph nodes

C772 = Intra-abdominal lymph nodes

C773 = Lymph nodes of axilla or arm

C774 = Lymph nodes:inguinal region or leg

C775 = Pelvic lymph nodes

C778 = Lymph nodes of multiple regions

C779 = Lymph node, NOS

C809 = Unknown primary site

**CCDE Item 11.06: Registry CS-derived SS2000**

Collaborative stage (CS)-derived summary stage 2001 [NAACCR data item #3020] obtained from the central cancer registry database. See CS Staging Manual at <http://www.cancerstaging.org> and the SEER Summary Staging Manual at [http://seer.cancer.gov](http://seer.cancer.gov/tools/ssm/) .

|  |  |
| --- | --- |
| **Value** | **Description** |
| 0 | In situ |
| 1 | Localized |
| 2 | Regional, direct extension |
| 3 | Regional, lymph nodes only |
| 4 | Regional, extension and nodes |
| 5 | Regional, NOS |
| 7 | Distant |
| 8 | Not applicable |
| 9 | Unknown/unstaged |

**CCDE Item 11.07: Registry CS-derived AJCC stage group**

Collaborative stage (CS)-derived AJCC stage [NAACCR data item #3000] obtained from the central cancer registry database WHEN AVAILABLE.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Value** | **Description** | **Value** | **Description** | **Value** | **Description** |
| 000 | Stage 0 | 322 | Stage IIA1 | 590 | Stage IIISB (lymphoma only) |
| 010 | Stage 0a | 323 | Stage IIA2 | 600 | Stage IIIS (lymphoma only) |
| 020 | Stage 0is | 330 | Stage IIB | 610 | Stage IIIESA (lymphoma only) |
| 100 | Stage I | 340 | Stage IIC | 620 | Stage IIIESB (lymphoma only) |
| 110 | Stage I NOS | 350 | Stage IIEA (lymphoma only) | 630 | Stage IIIES (lymphoma only) |
| 120 | Stage IA | 360 | Stage IIEB (lymphoma only) | 700 | Stage IV |
| 121 | Stage IA NOS | 370 | Stage IIE (lymphoma only) | 710 | Stage IV NOS |
| 130 | Stage IA1 | 380 | Stage IISA (lymphoma only) | 720 | Stage IVA |
| 140 | Stage IA2 | 390 | Stage IISB (lymphoma only) | 721 | Stage IVA1 |
| 150 | Stage IB | 400 | Stage IIS (lymphoma only) | 722 | Stage IVA2 |
| 151 | Stage IB NOS | 410 | Stage IIESA (lymphoma only) | 730 | Stage IVB |
| 160 | Stage IB1 | 420 | Stage IIESB (lymphoma only) | 740 | Stage IVC |
| 170 | Stage IB2 | 430 | Stage IIES (lymphoma only) | 888 | Not applicable |
| 180 | Stage IC | 500 | Stage III | 900 | Stage Occult |
| 190 | Stage IS | 510 | Stage III NOS | 999 | Stage Unknown |
| 230 | Stage ISA (lymphoma only) | 520 | Stage IIIA |  |  |
| 240 | Stage ISB (lymphoma only) | 530 | Stage IIIB |  |  |
| 200 | Stage IEA (lymphoma only) | 540 | Stage IIIC |  |  |
| 210 | Stage IEB (lymphoma only) | 541 | Stage IIIC1 |  |  |
| 220 | Stage IE (lymphoma only) | 542 | Stage IIIC2 |  |  |
| 300 | Stage II | 550 | Stage IIIEA (lymphoma only) |  |  |
| 310 | Stage II NOS | 560 | Stage IIIEB (lymphoma only) |  |  |
| 320 | Stage IIA | 570 | Stage IIIE (lymphoma only) |  |  |

**CCDE Item 11.08: Registry CS extension**

Collaborative stage (CS) extension [NAACCR data item #2810] obtained from the central cancer registry database. See CS Staging Manual at <http://www.cancerstaging.org>.

| **Value** | **Description for Colon** | **Description for Rectum** | **TNM 7** | **TNM 6** | **SS77** | **SS2000** |
| --- | --- | --- | --- | --- | --- | --- |
| 000 | In situ; noninvasive; intraepithelial  | In situ; noninvasive; intraepithelial  | Tis | Tis | IS | IS |
| 050 | (Adeno)carcinoma in a polyp or adenoma, noninvasive  | (Adeno)carcinoma in a polyp or adenoma, noninvasive  | Tis | Tis | IS | IS |
| 100 | Invasive tumor confined to mucosa, NOS, including intramucosal, NOS | Invasive tumor confined to mucosa, NOS, including intramucosal, NOS | Tis | Tis | L | L |
| 110 | Lamina propria, including lamina propria in the stalk of a polyp | Lamina propria, including lamina propria in the stalk of a polyp | Tis | Tis | L | L |
| 120 | Confined to and not through the muscularis mucosae, including muscularis mucosae in the stalk of a polyp | Confined to and not through the muscularis mucosae, including muscularis mucosae in the stalk of a polyp | Tis | Tis | L | L |
| 130 | Confined to head of polyp, NOS | Confined to head of polyp, NOS | T1 | T1 | L | L |
| 140 | Confined to stalk of polyp, NOS | Confined to stalk of polyp, NOS | T1 | T1 | L | L |
| 150 | Invasive tumor in polyp, NOS | Invasive tumor in polyp, NOS | T1 | T1 | L | L |
| 160 | Invades submucosa (superficial invasion), including submucosa in the stalk of a polyp | Submucosa (superficial invasion), including submucosa in the stalk of a polyp | T1 | T1 | L | L |
| 170 | Stated as T1[NOS] with no other information on extension | Stated as T1[NOS] with no other information on extension | T1 | T1 | L | L |
| 200 | Muscularis propria invadedStated as T2[NOS] with no other information on extension | Muscularis propria invadedStated as T2[NOS] with no other information on extenision | T2 | T2 | L | L |
| 300 | Localized, NOSConfined to colon, NOS | Localized, NOSConfined to rectum, NOS | T1  | T1  | L | L |
| 400 | Extension through wall, NOSInvasion through muscularis propria or muscularis, NOSNon-peritonealized pericolic tissues invadedPerimuscular tissue invadedSubserosal tissue/(sub)serosal fat invadedTransmural, NOS | Extension through wall, NOSInvasion through muscularis propria or muscularis, NOSPerimuscular tissue invadedSubserosal tissue/(sub)serosal fat invadedNon-peritonealized pericolic tissues invadedTransmural, NOS | T3 | T3 | L | L |
| 410 | Stated as T2[NOS] with no other information on extension | Stated as T2[NOS] with no other information on extension | T3 | T3 | L | L |
| 420 | Fat, NOS | Fat, NOS | T3 | T3 | RE | RE |
| 450 | Extension to:All colon sites:Adjacent tissue(s), NOSConnective tissueMesenteric fatMesenteryMesocolonPericolic fatAscending and descending colonRetroperitoneal fatTransverse colon/flexuresGastrocolic ligamentGreater omentum | Adjacent (connective) tissue:For all sites:Perirectal fatFor rectosigmoid:Mesentery (including mesenteric fat, mesocolon)Pericolic fatFor rectum:Extension to anusRectovaginal septum | T3 | T3 | RE | RE |
| 460 | Adherent to other organs or structures, but no microscopic tumor found in adhesion(s) | Adherent to other organs or structures but no tumor found in adhesion(s) | T3 | T3 | RE | RE |
| 490 |  | Stated as T4[NOS] with no other information on extension | T4NOS | T4 | RE | RE |
| 500 | Invasion of/through serosa (mesothelium) (visceral peritoneum) | Invasion of/through serosa (mesothelium) (visceral peritoneum) | T4a | T4 | RE | RE |
| 550 | Any of [(420) to (450)] + (500) | (500) with [(420) or (450)] | T4a | T4 | RE | RE |
| 560 | Stated as T4a with no other information on extension | Stated as T4a with no other information on extension | T4a | T4 | RE | RE |
| 570 | Adherent to other organs or structures, NOS | Adherent to other organs or structures, NOS | T4b | T4 | RE | RE |
| 600 | All colon sites:Small intestineCecum and appendix:Greater omentumAscending colon:Greater omentumLiver, right lobeTransverse colon and flexures:Gallbladder/bile ductsKidneyLiverPancreasSpleenStomachDescending colon:Greater omentumPelvic wallSpleenSigmoid colon:Greater omentumPelvic wall | Rectosigmoid:Cul de sac (rectouterine pouch)Pelvic wallSmall intestineRectum:Bladder for males onlyCul de sac (rectouterine pouch)Ductus deferensPelvic wallProstateRectovesical fascia for male onlySeminal vesicle(s)Skeletal muscle of pelvic floorVagina | T4b | T4 | RE | RE |
| 650 | All colon sites:Abdominal wallRetroperitoneum (excluding fat) |  | T4b | T4 | RE | RE |
| 660 | Ascending colon:Right kidneyRight ureterDescending colon:Left kidneyLeft ureter |  | T4b | T4 | RE | RE |
| 700 | Cecum, ascending, descending and sigmoid colon:Fallopian tubeOvaryUterus | Rectosigmoid:BladderColon via serosaFallopian tube(s)Ovary(ies)ProstateUreter(s)UterusRectum:Bladder for female onlyBone(s) of pelvisUrethraUterus | T4b | T4 | D | D |
| 750 | All colon sites unless otherwise stated above:Adrenal (suprarenal) glandBladderDiaphragmFistula to skinGallbladderOther segment(s) of colon via serosa |  | T4b | T4 | D | D |
| 800 | Further contiguous extension:Cecum and appendix:KidneyLiverUreterTransverse colon and flexures:UreterSigmoid colon:Cul de sac (rectouterine pouch)UreterOther contiguous extension | Further contiguous extension | T4b | T4 | D | D |
| 850 | Stated as T4b with no other information on extension | Stated as T4b with no other information on extension | T4b | T4 | RE | RE |
| 900 | Stated as T4[NOS] with no other information on extension | Stated as T4[NOS] with no other information on extension | T4NOS | T4 | RE | RE |
| 950 | No evidence of primary tumor | No evidence of primary tumor | T0 | T0 | U | U |
| 999 | Unknown extensionPrimary tumor cannot be assessedNot documented in patient record | Unknown extensionPrimary tumor cannot be assessedNot documented in patient record | TX | TX | U | U |

**CCDE Item 11.09: Registry CS lymph nodes**

Collaborative stage (CS) lymph nodes [NAACCR data item #2830] obtained from the central cancer registry database. See CS Staging Manual at <http://www.cancerstaging.org>.

| **Value** | **Description for Colon** | **Description for Rectum** | **TNM 7** | **TNM 6** | **SS77** | **SS2000** |
| --- | --- | --- | --- | --- | --- | --- |
| 000 | None; no regional lymph node involvement  | None; no regional lymph node involvement  | N0 | N0 | None | None |
| 050 | Tumor deposit(s) in the subserosa, or non-peritonealized pericolic or perirectal tissues without regional nodal metastasis | Tumor deposit(s) in the subserosa, or non-peritonealized pericolic or perirectal tissues without regional nodal metastasis | N1c | N1 | RN | RN |
| 100 | Regional lymph node(s) for all colon sites:Colic (NOS)Epicolic (adjacent to bowel wall)Mesocolic (NOS)Paracolic/pericolic | Regional lymph node(s):Rectosigmoid:Paracolic/pericolicPerirectalRectalNodule(s) or foci in pericolic fat/adjacentmesentery/mesocolic fatRectum:PerirectalRectal, NOSNodule(s) or foci in perirectal fat | ^ | \* | RN | RN |
| 200 | Regional lymph node(s), for specific subsites:Cecum:Cecal: anterior (prececal), posterior (retrocecal); NOSIleocolicRight colicAscending colon:IleocolicMiddle colicRight colicTransverse colon and flexures:Inferior mesenteric for splenic flexure onlyLeft colic for splenic flexure onlyMiddle colicRight colic for hepatic flexure onlyDescending colon:Inferior mesentericLeft colicSigmoidSigmoid colon:Inferior mesentericSigmoidal (sigmoid mesenteric)Superior hemorrhoidalSuperior rectal | Regional lymph node(s):Rectosigmoid:Colic, NOSLeft colicHemorrhoidal, superior or middleInferior mesentericMiddle rectalSigmoidal (sigmoid mesenteric)Superior rectalRectum:Hemorrhoidal, superior, middle or inferiorInferior mesentericInternal iliac (hypogastric)ObturatorRectal, superior, middle, or inferiorSacral, NOSLateral (laterosacral)Middle (promontorial) (Gerota's node)PresacralSacral promotorySigmoidal (sigmoid mesenteric) | ^ | \* | RN | RN |
| 300 | Regional lymph node(s) for all colon sites:Mesenteric, NOSRegional lymph node(s), NOS | Mesenteric, NOSRegional lymph node(s), NOS | ^ | \* | RN | RN |
| 400 | Stated as N1 pathologic | Stated as N1 pathologic | N1NOS | N1 | RN | RN |
| 410 | Stated as N1a pathologic | Stated as N1a pathologic | N1a | N1 | RN | RN |
| 420 | Stated as N1b pathologic | Stated as N1b pathologic | N1b | N1 | RN | RN |
| 450 | Stated as N2 pathologic | Stated as N2 pathologic | N2NOS | N2 | RN | RN |
| 460 | Stated as N2a pathologic | Stated as N2a pathologic | N2a | N2 | RN | RN |
| 470 | Stated as N2b pathologic | Stated as N2b pathologic | N2b | N2 | RN | RN |
| 800 | Lymph nodes, NOS | Lymph nodes, NOS | ^ | \* | RN | RN |
| 999 | Unknown; not statedRegional lymph node(s) cannot be assessedNot documented in patient record | Unknown; not statedRegional lymph node(s) cannot be assessedNot documented in patient record | NX | NX | U | U |

^ and \* For codes 100-300 and 800 ONLY, please see collaborative stage manual for specific coding instructions.

**CCDE Item 11.10: Registry CS mets at diagnosis**

Collaborative stage (CS) metastases (mets) at diagnosis obtained from the central cancer registry database. North American Association of Central Cancer Registries (NAACCR) data item #2850. See the CS Staging Manual at [http://www.cancerstaging.org](http://www.cancerstaging.org/cstage/csmanualpart2.pdf) .

| **Value** | **Description for Colon** | **Description for Rectum** | **TNM 7** | **TNM 6** | **SS77** | **SS2000** |
| --- | --- | --- | --- | --- | --- | --- |
| 00 | No; none | No; none | M0 | M0 | None | None |
| 05 |  | Metastasis to a single distant lymph node chain, NOS | Ma1 | M1 | D | D |
| 08 | Cecum, ascending, hepatic flexure and transverse colon:Superior mesenteric lymph node(s) only |  | M1a | M1 | RN | D |
| 15 | Metastasis to a single distant lymph node chain other than code 08For all colon sites :Common iliacDistant lymph node(s), NOSExternal iliacPara-aorticRetroperitonealFor cecum, ascending colon, transverse colon, and hepatic flexure :Inferior mesentericFor splenic flexure, descending colon, and sigmoid colon :Superior mesenteric | Metastasis to a single distant lymph node chainRectosigmoid :Internal iliac (hypogastric)Obturator | M1a | M1 | D | D |
| 20 | Metastasis to a single distant organ | Metastasis to other single distant lymph node chains, includingexternal iliac or common iliac | M1a | M1 | D | D |
| 22 | Stated as M1a with no other information on distant metastases |  | M1a | M1 | D | D |
| 25 | Metastasis to more than one distant lymph node chain other than code 08For all colon sites :Common iliacDistant lymph node(s), NOSExternal iliacPara-aorticRetroperitonealFor cecum, ascending colon, transverse colon, and hepatic flexure :Inferior mesentericSuperior mesentericFor splenic flexure, descending colon, and sigmoid colon : Superior mesenteric | Metastasis to a single distant organ | M1b | M1 | D | D |
| 27 |  | Stated as M1a, NOS | M1a | M1 | D | D |
| 30 | Metastases to more than one distant organMetastases to the peritoneumCarcinomatosis | Metastasis to more than one distant lymph node chain | M1b | M1 | D | D |
| 35 | (08 or 15 or 25) PLUS 20 or 30) Distant lymph nodes plus other distant metastases | Distant metastases to more than one distant organMetastases to the peritoneumCarcinomatosisStated as M1b, NOS | M1b | M1 | D | D |
| 38 | Stated as M1b with no other information on distant metastases |  | M1b | M1 | D | D |
| 45 |  | (05 or 15 or 20) plus (25 or 35)Distant lymph node(s) plus other distant metastases | M1b | M1 | D | D |
| 60 | Distant metastasis, NOSStated as M1[NOS] with no other information on distant metastases | Distant metastasis, NOSM1, NOS | N1NOS | M1 | D | D |
| 99 | Unknown if distant metastasisDistant metastasis cannot be assessedNot documented in patient record | Unknown if distant metastasisDistant metastasis cannot be assessedNot documented in patient record | M0 | MX | U | U |

The following values for Colon are obsolete. They have been excluded from this table but will be considered valid responses if reported: 10, 40 and 50.

The following values for Rectum are obsolete. They have been excluded from this table, but will be considered valid responses if reported: 10, 11, 12, 40 and 50

**CHAPTER 4**

**References**

**Appendix A**

**CCDE Submission**

**Narrative Guidelines**

CCDE Submission Narrative Guidelines

January 1, 2010

The submission narrative provides a structured way for grantees to respond to questions or issues identified during the CCDE data review.

The submission narrative is comprised of two sections:

1. The first section should include written responses to any action items that were identified in the previous data submission. Following the review and discussion of the grantee’s CCDE data file by the CDC Program Consultant, CDC Scientific Consultant and IMS Clinical Data Technical Consultant and grantee staff, an Action Plan will be developed. The CDC Program Consultant will provide this information to the appropriate staff at the program. Each action item should be addressed by the grantee in this first section.

II. The second section should address the following questions. If the question is not applicable to your program at this time, please indicate “N/A”:

1. Summarize reasons for any significant data issues identified by the program but not resolved prior to submitting the CCDE file to the CDC.

2. Identify any modifications made to the software which generates the CCDE file that would cause significant changes in the distribution of the values for individual data items.

1. Identify any batch recoding of records in the CCDE file that would cause significant changes in the distribution of the values for individual data items.
2. Identify any data management staffing, system, or procedural changes that would affect the data management capacity. Examples of these include staff turnover, revision of data collection forms, revision of data entry screens, a change in the data collection model (i.e. centralized to decentralized), etc.
3. Identify any plans to significantly upgrade existing data management software, or to develop and migrate the client database to a new data management system.

**SAMPLE**

CCDE Submission Narrative for Your Program

September 2010 Submission

Part 1. Action Item Responses

**Standard Quality Indicator Guide (SQIG)**

Item 8: There are several records where Status of Final Diagnosis = Complete, but the Final Diagnosis and Date of Final Diagnosis are missing.
***RESPONSE: We used the CCDE Edit program to identify 20 records with incomplete data. These records were reviewed and corrected.***

Item 10: The CDC provides a recommendation that at least 80% of clients should take less than 60 days from the beginning of screening until final diagnosis. Your program does not meet this recommendation. Please discuss causes for the delay between screening and diagnosis.
***RESPONSE: While reviewing the cases we have discovered some reporting issues. At the time of submission, we continue to evaluate all the causes for the delay in timeliness. We will report on any findings as soon as possible.***

Part 2: Address the following questions:

1. Summarize reasons for any significant data issues identified by the program but not resolved prior to submitting the CCDE file to the CDC.
***Please see response to SQIG Item 10.***
2. Identify any modifications made to the software which generates the CCDE file that would cause significant changes in the distribution of the values for individual data items.
***Not applicable.***
3. Identify any batch recoding of records in the CCDE file that would cause significant changes in the distribution of the values for individual data items.
***We modified how our export program creates the record ID. The record ID has been changed for all records reported in this submission.***
4. Identify any data management staffing, system, or procedural changes that would affect the data management capacity.
***Not applicable.***
5. Identify any plans to significantly upgrade existing data management software, or to develop and migrate the client database to a new data management system.
***Not applicable.***

**APPENDIX B**

**CDC RACE AND**

**ETHNICITY CODE SET**

**TABLE 1 – RACE CONCEPTS AND CODES**

| **CCDE Category** | **Concept** |
| --- | --- |
| 1. White | European (which may include:) |
|  |  Armenian |
|  |  English |
|  |  French |
|  |  German |
|  |  Irish |
|  |  Italian |
|  |  Polish |
|  |  Scottish |
|  | Middle Eastern or North African (which may include:) |
|  |  Assyrian |
|  |  Egyptian |
|  |  Iranian |
|  |  Iraqi |
|  |  Lebanese |
|  |  Palestinian |
|  |  Syrian |
|  |  Afghanistani |
|  |  Israeli |
|  | Arab |
|  |  |
| 2. Black or African American | Black |
|  | African American |
|  | African (which may include:) |
|  |  Botswanan |
|  |  Ethiopian |
|  |  Liberian |
|  |  Namibian |
|  |  Nigerian |
|  |  Zairian |
|  | Bahamian |
|  | Barbadian |
|  | Dominican |
|  | Dominican Islander |
|  | Haitian |
|  | Jamaican |
|  |  |
| 2. Black or African American (cont’d) | Tobagoan |
|  | Trinidadian |
|  | West Indian |
|  |  |
| 3. Asian | Asian Indian |
|  | Bangladeshi |
|  | Bhutanese |
|  | Burmese |
|  | Cambodian |
|  | Chinese |
|  | Taiwanese |
|  | Filipino |
|  | Hmong |
|  | Indonesian |
|  | Japanese |
|  | Korean |
|  | Laotian |
|  | Malaysian |
|  | Okinawan |
|  | Pakistani |
|  | Sri Lankan |
|  | Thai |
|  | Vietnamese |
|  | Iwo Jiman |
|  | Maldivian |
|  | Nepalese |
|  | Singaporean |
|  | Madagascar |
|  |  |
| 4. Native Hawaiian or Other Pacific Islander | Polynesian (which may include:) |
|  |  Native Hawaiian |
|  |  Samoan |
|  |  Tahitian |
|  |  Tongan |
|  |  Tokelauan |
|  | Micronesian (which may include:) |
|  |  Guamanian |
|  |  Chamorro |
|  |  Mariana Islander |
|  |  Marshallese |
| 4. Native Hawaiian or Other Pacific Islander (Cont’d) |  Palauan |
|  |  Carolinian |
|  |  Kosraean |
|  |  Pohnpeian |
|  |  Yapese |
|  |  Saipanese |
|  |  Kiribati |
|  |  Chuukese |
|  | Melanesian (which may include:) |
|  |  Fijian |
|  |  Papua New Guinean |
|  |  Solomon Islander |
|  |  New Hebrides |
|  | Other Pacific Islander |
|  |  |
| 5. American Indian or Alaskan Native | American Indian |
|  | Canadian and Latin American Indian (which may include:) |
|  |  Canadian Indian |
|  |  Central American Indian |
|  |  French American Indian |
|  |  Mexican American Indian |
|  |  South American Indian |
|  |  Spanish American Indian |
|  | Alaskan Native (which may include:) |
|  |  Alaskan Indian |
|  |  Inuit |
|  |  Aleut |

**TABLE 2 – ETHNICITY CONCEPTS AND CODES**

|  |  |
| --- | --- |
| **CCDE Category** | **Concept** |
| Hispanic or Latino | Spaniard |
|  | **Mexican** |
|  | **Central American** |
|  | **South American** |
|  | **Latin American** |
|  | **Puerto Rican** |
|  | **Cuban** |
|  | **Dominican** |
|  |  |
| Not Hispanic or Latino |  |

**APPENDIX C**

**CCDE DATA DEFINITION TABLE**

**APPENDIX D**

**GLOSSARY OF TERMS**

|  |  |
| --- | --- |
| ACS: | <http://www.cancer.org> |
| Adenomatous polyp | See “Polyp”. More likely to develop into cancer than a non-adenomatous polyp. Also known as “adenoma”.  |
| CDC CRCCP Home Page: | <http://www.cdc.gov/cancer/crccp/> |
| CO-RADS | Colonoscopy Reporting and Data System (CO-RADS), a standardized colonoscopy reporting and data system. CO-RADS specifies the elements that should be included in all colonoscopy reports and presents a standard method for reporting them. |
| Colonoscope: | A flexible, lighted instrument with a built-in tiny camera used to view the inside of the entire colon and rectum. |
| Colonoscopy: | An examination in which the doctor looks at the internal walls of the entire colon through a flexible, lighted instrument called a colonoscope. The doctor may collect samples of tissue or cells for closer examination. The doctor may also remove polyps during colonoscopy. |
| Colorectal: | Related to the colon, rectum or both. |
| CRCCP Resource Web Site: | [www.CRCCP.org](http://www.crcsdp.org) |
| CS Coding Manual: | [www.cancerstaging.org](http://www.cancerstaging.org)  |
| Double-Contrast Barium Enema | A series of x-rays of the colon and rectum. The x-rays are taken after the patient is given an enema, followed by an injection of air. The barium outlines the intestines on the x-rays, allowing many abnormal growths to be visible. |
| Fecal Immunochemical Test (FIT) | Like a fecal occult blood test (FOBT), an FIT also detects hidden blood in the stool using a different technique than guaiac based FOBT. FIT is effectively done the same way as an FOBT, but it may be more specific or more sensitive than a guaiac based FOBT. |
| Fecal Occult Blood Test (FOBT) | A guaiac based test to check for hidden blood in stool. Fecal refers to stool. Occult means hidden. Sometimes called "F.O.B.T.". |
| Flexible Sigmoidoscopy  | A procedure in which the doctor looks inside the rectum and the lower portion of the colon (sigmoid colon) through a flexible, lighted tube called a sigmoidoscope. The doctor may collect samples of tissue or cells for closer examination and remove some polyps within view. |
| Gastroenterologist | A doctor who specializes in diagnosing and treating disorders of the digestive system (which includes the esophagus, stomach, pancreas, intestines, and liver). |
| Polyp | An abnormal, often precancerous growth of tissue (colorectal polyps are growths of tissue inside the intestine). |
| Rectum | The last 8 to 10 inches of the large intestine. The rectum stores solid waste until it leaves the body through the anus. |
| Screening Test | "Screening tests" are tests used to check, or screen, for disease when there are no symptoms. Screening tests for colorectal cancer include: fecal occult blood test, flexible sigmoidoscopy, colonoscopy, and double contrast barium enema. (When a test is performed to find out why symptoms exist, it is called a "diagnostic" test). |
| SEER Coding Manual: | [www.seer.cancer.gov](http://www.seer.cancer.gov)  |
| Sigmoidoscope | A flexible, lighted instrument with a built-in tiny camera that allows the doctor to view the lining of the rectum and lower portion of the colon. |
| Stool DNA | A stool DNA test looks for traces of DNA (genetic material) shed by polyps and/or colorectal tumors. |
| Virtual Colonoscopy | A screening examination of the colon in which x-rays obtained by CAT scan are used to generate computerized three-dimensional images of the colonic mucosa. |