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CONNECTICUT CANCER AND HEART DISEASE INTEGRATED HEALTH SCREENING PROGRAM (CCHDIHSP)

CLINICAL DATA COLLECTION AND REPORTING MANUAL

JULY 1, 2013

REQUIREMENTS FOR REPORTING PROGRAM DATA TO THE CENTERS FOR DISEASE CONTROL AND PREVENTION



Well-integrated Screening and Evaluation
for Women Across the Nation



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INTRODUCTION

ACCOUNTABILITY:

The CCHDIHSP is publicly funding with money from both the state and federal governments. As such, there are extensive requirements for documentation and reporting that must be adhered to. These include:

- Electronic collection and reporting of Minimum Data Elements,
- Compliance with Performance Measures,
- Oversight and stewardship of prudent expenditures,
- Optimization of program resources as payor of last resort,
- Adherence to contract administration and compliance procedures, and
- Continuous monitoring, evaluation, and program improvement.

The “unit of measure” for reporting program services is determined by the Centers for Disease Control and Preventions (CDC) as the “screening cycle.” A screening cycle has a definitive start and a definitive end, each with its own criteria. Screening cycles begin with the conducting of a screening test and conclude with a final determination of the disease status. Services are specific to the early detection of diseases specified within the constructs of the publicly funded program.

Every attempt should be made to synchronize screening services into ONE integrated screening office visit (clinical examination visit for early detection screening purposes).

Data may be collected on CDC-approved data collection forms as supplied by the Connecticut Department of Public Health (DPH) or may be entered directly into the medical information and tracking system (Med-IT®) used by the DPH that was specifically designed for reporting NBCCEDP and WISEWOMAN Minimum Data Elements and CRCCP Colorectal Cancer Data Elements to the CDC. Med-IT® access may be granted to anyone with an internet connection, as specified by the program contact. It is typically up to the Site Coordinator to determine who will be given access to the Med-IT system and to what degree of privileges they will be granted. It is important to understand that the Med-IT® system is not the primary electronic medical record. The Med-IT® system is simply a data management tool used for data collection, analysis and reporting of program-related activity to the CDC, in a format as specified by the CDC.

Screening Cycles as a Unit of Measure

Breast Cancer Screening Cycle:

Breast Cancer Screening Cycle –female only (typically expected to be completed within 60 days)
Cycle typically begins with: Clinical Breast Exam and Age-appropriate mammogram (women ≥ 40 years)

*participants may be referred into the program with test results from a non-program provider, and the screening cycles could begin with a diagnostic procedure.

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Cycle typically ends with: normal screening test results or a final diagnosis concluding the outcome of an abnormal screening test result.

*Participants may refuse recommended procedures and/or sever contact with program staff and the cycle will be closed to reflect such outcome.

Cervical Cancer Screening Cycle

Cervical Cancer Screening Cycle – female only (typically expected to be completed within 90 days)

Cycle typically begins with: an interval-appropriate Pap test (women ≥ 21 years of age). It's important to note that a pelvic exam is not a screening test and although may accompany a Pap test, does not initiate a screening cycle.

*Participants may be referred into the program with abnormal screening test results from a non-program provider and the screening cycle would begin with documentation of the non-program results and the initiation of diagnostic follow-up services.

Cycle typically ends with: normal screening test results or a final diagnosis concluding the outcome of an abnormal screening test result.

*Participants may refuse recommended procedures and/or sever contact with program staff and the cycle will be closed to reflect such outcome.

Heart Disease Risk Factor Screening Cycle

Heart Disease Risk Factor Screening Cycle –female only (typically expected to be completed within 12-18 months)

Cycle typically begins with: the breast and cervical cancer screening visit for women ≥ 40 years of age and includes a fasting blood test for cholesterol and glucose values in conjunction with the completion of a health assessment questionnaire.

*Participants may choose not to have their blood tested, however they should be encouraged to participate fully for the best assessment of modifiable risk factors contributing to heart disease and for the best outcome from risk reduction and lifestyle intervention counseling.

Cycle typically ends with: a rescreening visit to be conducted with next breast and cervical cancer screening cycle at the 12-18 month interval.

*Participants may refuse recommended procedures and/or sever contact with program staff and the cycle will be closed to reflect such outcome.

Colorectal cancer screening cycle

Colorectal cancer screening cycle– male or female:

Cycle typically begins with: the client 50-64 years old being determined eligible for, and wanting a colonoscopy. The minimum data for this screening cycle is a scheduled date for the colonoscopy.

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Cycle typically ends with: a final diagnosis of colon cancer or no colon cancer and a recommendation for when to perform the next colonoscopy.

*Participants may refuse recommended procedures and/or sever contact with program staff and the cycle will be closed to reflect such outcome.

ENROLLMENT FORM

All participants must be determined eligible for and due for program services BEFORE program services are provided. Program funding will not be used to reimburse services that fall outside of program guidance and program participants cannot be billed for program services that were not reimbursed with program funds. Provider staff should ALWAYS review the enrollment form to ensure it was completed correctly and discuss with the participant any questions, discrepancies or missing information. Although some questions may appear invasive or embarrassing, accurate information helps assure continued funding for underserved populations and providers should approach participants with supportive encouragement to complete all enrollment questions.

Eligibility criteria is routinely updated and may be found on the DPH website at <http://www.ct.gov/dph> under Services and Programs; Cancer. Eligibility is based on income, age and insurance status. Income must be at or below 250% of the Federal Poverty Level and participants who are not at or below the 250% Federal Poverty Level will likely not qualify for the “Cancer Treatment Act” if breast or cervical cancer should be detected. Income is self-reported so it’s important that you gain trust and communicate the importance of an accurate accounting. Record income earned before taxes, the frequency of the income, and the number of people in the household that live on the income. Eligibility calculations are made automatically in the Med-IT® eligibility screen.

Insurance Status documentation is required to determine eligibility. A participant may have insurance and still qualify if the insurance policy has a deductible greater than \$1,000 or if the insurance policy does not cover screening services provided by this program. A participant with a Medicaid spend-down can qualify until the spend-down has been reached.

Tobacco Use: Connecticut is required to have a policy for assessing the tobacco use of each participant being screened and to make referrals to the Connecticut Tobacco Quit Line. This policy is in addition to tobacco assessment and cessation activities that are part of the Heart Disease Modifiable Risk Factor Screening. The Tobacco Use Policy requires that tobacco use be assessed for each participant at the beginning of each new screening cycle (usually on an annual basis with routine breast cancer screening and always during the first enrollment).

Services Requested / Eligible Services: The enrollment form allows for documentation of both, the services being requested by a participant and for those services which follow program guidance and are considered by program staff to be timely, appropriate, and reimbursable with program funds (eligible for). It’s important to check the Med-IT® system for any previous program history before services are

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scheduled and to alert the participant on what will be covered with program funds. All participants must be determined eligible for, and due for services BEFORE services are provided.

Program funding will not be used to reimburse services that fall outside of program guidance and program participants cannot be billed for program services that were not reimbursed with program funds. The Med-IT® system holds records dating back to 1995 and will provide guidance on what services are timely and appropriate. Use more than one search option when looking for a client in Med-IT® as names may be misspelled and numbers may be transposed or improperly recorded.

Primary Care Physician: It's important to identify where a participant receives primary medical care. All participants enrolled in the CCHDIHSP for colorectal cancer screening MUST first be enrolled with a primary care provider. All participants who present to the program and found to be medically ineligible for a colonoscopy must be referred outside the program for additional services and evaluation. All participants receiving heart health screening and found to have an abnormal screening value are to be referred outside the program for medical evaluation. Participants with "alert" values (very high values) are required to be referred outside the program for immediate medical evaluation to occur within 7 days of the alert finding.

Contact and Alternate Contact Information: It is important to collect as much contact information as possible. Participants may be difficult to re-contact as residences and phone numbers provided during enrollment could be temporary. Language barriers may also interfere with a successful encounter and alternate contact information of a friend or significant other may be beneficial. It may not be appropriate to use an adult child relationship for an alternate contact as final diagnosis may need to be more private. Be sure to ask about internet and e-mail access.

Cultural Characteristics: DPH has a formal policy on collecting socio-demographic data. Enrollment forms are designed to comply with this policy. It is very important to respect the need for these data points. Included in this policy is the need to collect data on subcategories of ethnicity and certain races and to collect information on language preferences and residential history.

Cultural Characteristics - Ethnicity: Subcultures of Hispanic ethnicity are required to be collected by DPH policy.

Cultural Characteristics - Race Subcultures of Asian and Hawaiian/Pacific Islander races are required to be collected by DPH policy. If a participant reports race as Hispanic or Latino, the ethnicity should be recorded as Hispanic and the race may be recorded as unknown.

Demographics: DPH has a formal policy on collecting socio-demographic data. Enrollment forms are designed to comply with this policy. It is very important to respect the need for these data points. Collect as much information as you can about

- Language preferences – this data is used to craft program literature
- Residential history – documents length of stay in the U.S.

- Employment status – document employment status
- Referral source for learning about the program – this information is valuable in crafting and evaluating the success of outreach activities
- Level of education – education is a field CDC requires to be collected. Enter educational attainment by number of years of schooling. If participants are reluctant to provide this information, explain how important it is to have accurate information that helps document the need for public programs that reach populations at risk for not receiving adequate health care.

Health disparities and barriers to care can often be related to issues of culture, language, education, and income. It is important that these data are collected completely and accurately to help document the need for public assistance to reach populations at risk for not receiving adequate health care. When enrolling participants, it is also very important to record how they learned about the program. This data aids in developing successful outreach activities for your service areas.

Breast Health History is collected and recorded only once, at the very first enrollment into the program. If a participant leaves and then returns to the program, the date of the prior mammogram remains as the date recorded with the first enrollment and screening visit. The date of a prior mammogram is the date of the mammogram before this current screening cycle. Any non-program mammogram that supports enrollment into the program should NOT be used as the prior mammogram. The prior mammogram is the mammogram before the referral mammogram.

Cervical Health History is collected and recorded only once, at the very first enrollment into the program. If a participant leaves and then returns to the program, the date of the prior Pap test remains as the date recorded with the first enrollment and screening visit. The date of a prior Pap test is the date of the Pap test before this current screening cycle. Any non-program Pap test that supports enrollment into the program should NOT be recorded as the prior Pap test. The prior Pap test is the Pap test before the referral Pap test.

Previous Colorectal Cancer Screening History is collected to determine medical eligibility and should be updated prior to scheduling a colorectal cancer screening procedure. A client is typically not eligible for a screening colonoscopy if they have had a colonoscopy within the previous 10 years.

Current Colorectal Health History is also collected to determine medical eligibility for a colorectal cancer screening and should be updated prior to scheduling a procedure. A client must be considered at normal or possibly increased risk to qualify for a program-funded colonoscopy. A participant with the following history (considered high risk) is not eligible for a colonoscopy under this program:

- Previous personal history of colorectal cancer
- The genetic diagnosis of familial adenomatous polyposis (FAP) or Lynch Syndrome (hereditary non-polyposis colorectal cancer or NHPCC)
- A clinical diagnosis or suspicion of familial adenomatous polyposis (FAP) or Lynch Syndrome, or
- A history of inflammatory bowel disease (IBD) (ulcerative colitis or Crohn's disease).

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CRC Date of Scheduled Procedure: If a participant is deemed both financially and medically eligible for a screening colonoscopy, a date for the procedure is required to be established and recorded and patient navigation activity begins. Adherence to that scheduled date will be collected and recorded later in the screening documentation process.

Notes for Colonoscopy: This is a free form area for collecting information about the scheduled procedure. These notes are specific to the scheduled colonoscopy and are not considered required documentation.

Barriers for Access to Continuing Health Care: There are many issues that may interfere with a participant's ability to comply with clinical recommendations. These issues are referred to as "barriers" for access to continuing health care. Barriers are required to be determined as part of the formal Needs Assessment protocol when a breast or cervical cancer screening test is determined as abnormal. Identifying barriers at the enrollment process may also alert the provider to potential issues for making and/or keeping mammogram appointments, blood test appointments, colonoscopy appointments and successful participating in risk reduction counseling and life style intervention activities. During the enrollment process you may encourage participants to document all applicable barriers and factor those into your health navigation activities for this program.

Example Barriers:

- Language Issues – Doesn't speak English, doesn't have a translator
- Religious Beliefs – beliefs conflict with medical practices
- Potential Discomfort of Procedure –unwilling to feel discomfort or anticipates pain worse than it will be
- Cultural Differences – has to get permission from her husband or is ashamed of genital mutilation
- Concerns about Sex – doesn't want to share sexual activity, afraid others will find out she's not a virgin
- Relationship with Significant Other – doesn't have support of partner
- Lack of Transportation – unable to get to the doctor's office
- Child/Elder Care – unable to leave the house while others are home
- Understanding of the Medical Need: inability to understand the consequences of not getting diagnosed
- Getting Time from Work: unable to ask for time away from work
- Finances / Money: Doesn't have any money to cover a procedure
- Confusion about Covered Services: doesn't understand what will be paid for
- A Disability or Impairment : can't hear, see or walk
- Making the Appointment: doesn't know what to say when asked why she needs an appointment
- Fear of Being Diagnosed with Cancer –
- Fear of Losing Intimacy after Procedure
- Fear of Losing Employment if Diagnosed with Illness
- Other: anything that cannot be categorized in one of the choices above

Client Notes are notes that may be collected on the client and entered into the Med-IT® system for future referral. The client notes are specific to the individual participant, regardless of the screening services or screening cycles that are being conducted. Client notes may be useful references throughout the participant's history in the program.

SCREENING AND ASSESSMENT FORM

Clinical Office Visit Documentation: The CDC requires specific information regarding why a participant in coming in for program services. This is referred to as the reason a screening cycle is being initiated or **cycle initiation**. The CDC has staff to analyze the types and frequencies of services being provided through the program to provide an overview to Congress of how program services are being delivered and to portray the impact the program has on the health of the population it serves. It's important that CDC staff are able to identify the clinical scenario which resulted in a specific course of action. For this reason, providers are required to identify the reason a participant is coming in for a breast cancer screening mammogram (**Indication for Mammogram**) or a cervical cancer screening Pap test (**Indication for Pap test**) and to document that reason in Med-IT® as an MDE. It is also important to identify the reasons for delivering heart health screening and colorectal cancer screening services to properly document those screening cycles.

Breast Cancer Screening - Indication for Mammogram: The target population for the CBCCEDP is women 50 to 64 years of age. Seventy-five 75% of women receiving screening mammograms are required to be between this age range. As such, the indication for a breast cancer screening cycle is referred to as the indication for mammogram. The following choices are available for completing this data collection requirement.

- **Routine screening mammogram** (this category is used if the initial mammogram was performed as part of a routine or annual screening schedule and in the absence of symptoms or a recent positive CBE)
- **Initial mammogram performed to evaluate symptoms, positive/suspicious CBE result or previous abnormal mammogram result** (this category is used if the initial mammogram was performed as additional evaluation of a recent mammogram prior to this cycle, evaluation of current symptoms or abnormal CBE finding.)
- **Initial mammogram done outside of the Program and referred into the Program for diagnostic evaluation** (this category is used if the initial mammogram was performed outside of the Program and the participant was referred into the Program for diagnostic evaluation)
- **Initial mammogram not done - Patient only received only CBE or proceeded directly for other imaging or diagnostic work-up** (this category is typically used for women under 40 years of age who are not medically eligible for a screening mammogram and those women who are returning for a 6 month follow-up unilateral diagnostic mammogram from a previous abnormal diagnosis.)
- **Cervical record only, breast services not done** (this category is used if no CBE or breast cancer screening mammogram services were provided or reported in this record.)

Cervical Cancer Screening - Indication for Pap Test: The initial screening test for cervical cancer is the Papanicolaou (Pap) test. As such, the indication for a cervical cancer screening cycle is referred to as the indication for Pap test. The following choices are available for completing this data collection requirement.

- **Routine Pap test** (this category is used if the Pap test was performed as part of a routine screening schedule or when a new screening cycle is created to re-do a previously unsatisfactory Pap test.)
- **Patient under surveillance for a previous abnormal test** (this category is used if the Pap test was performed for a participant under management for a cervical abnormality detected prior to this cycle and is required to come back at an interval sooner than what is recommended for routine screening)
- **Pap test done outside of the Program and patient referred into the Program for diagnostic evaluation** (this category is used if the Pap test was performed outside of the Program and the participant was referred to the Program for diagnostic evaluation. The date and result of the non-program Pap test is then recorded and may be entered in the cycle initiation screen of the Med-IT® system.)
- **Pap test not done - Patient proceeded directly for diagnostic work-up or HPV testing** (this category is used when a participant did not have a program-funded Pap test and went directly to HPV testing, colposcopy, or other diagnostic procedure. This category should rarely be used as most diagnostic work is dependent upon the abnormal results of a Pap test.)
- **Breast record only, cervical services not done** (this category is used if no Pap test or diagnostic cervical services were provided or reported in this record). A pelvic exam is not a screening test for cervical cancer.

HD Risk Factor Screening – Indication for HD Screening Cycle: The intent for screening is to establish baseline values, provide risk reduction and lifestyle intervention activities and to establish rescreening values as a measure to indicated change in risk. Women will typically be seen once for their baseline visit and once for their rescreening visit. An abnormal non-fasting blood test result may require an additional diagnostic visit to conduct a fasting blood test. In rare occasions, a participant may receive another full session of services, referred to as “other” rescreening. And, similar to Pap testing intervals, CT considers a participant who has not been screened in five or more years to be considered as rarely or never screened and to eligible for the program services once again.

- **Coordinated Baseline Screening** (this category is used for the first time in the current contract period that a participant is receiving a screening for modifiable risk factors of heart disease.)
- **Diagnostic Blood Test** (this category is used when a participant with non-fasting abnormal blood test values has to return for a fasting blood test.)
- **Coordinated Rescreening Visit** (this category is used for the second time in the current contract period when the participant return after a year of risk reduction and lifestyle intervention counseling. This visit should be coordinated with the breast and cervical services that may be due at the annual screening interval of 12-18 months)
- **Additional “other” rescreening** (this category is used if authorization was obtained from DPH to allow for the participant to cycle through the program for another year.)
- **New Baseline (post 5-year)** (this category is used for women considered rarely or never screened, those who have been screened before, but that have not had their modifiable risk factors for heart disease assessed within the last 5 years.)

Colorectal Cancer Screening – Indication for CRC Screening Cycle

- **First screening test (Cycle 1)** (this category is used for the first screening colonoscopy provided by the program and is to be coded as a screening colonoscopy)
- **Second Screening Test (Cycle 1)** (this category is used for subsequent procedures that may need to be performed as a result of the first screening colonoscopy. This second screening test may include a repeat colonoscopy if the prep was not adequate or if the cecum was not reached. There may also be a need to repeat the colonoscopy if all polyps could not be completely removed in the first procedure. This category is also used to record non-program procedures such as sigmoidoscopy or colonography that were needed to complete a diagnosis but were not reimbursable with program funds.)
- **Third Screening Test (Cycle 1)** This category will likely never be used as a diagnosis is typically reached by completion of the second procedure. However, if additional procedures are warranted, regardless of the pay source, the outcome needs to be recorded in the screening record and a final diagnosis documented. An example of this would be 2 incomplete colonoscopies and a recommendation for a visual colonoscopy or a barium enema to reach final diagnosis. The virtual colonoscopy and barium enema are not reimbursable with program funds, but need to be recorded as part of the screening and diagnostic process to reach a final diagnosis of cancer or no cancer.
- **Fourth Screening Test (Cycle 1)** This category will likely never be used as a diagnosis is typically reached by completion of the second procedure. However, if additional procedures are warranted, regardless of the pay source, the outcome needs to be recorded in the screening record and a final diagnosis documented. An example of this would be 2 incomplete colonoscopies and a recommendation for a visual colonoscopy or a barium enema to reach final diagnosis. The virtual colonoscopy and barium enema are not reimbursable with program funds, but need to be recorded as part of the screening and diagnostic process to reach a final diagnosis of cancer or no cancer.

Anthropometric measures: In the course of delivering clinical services it is best practice to take and record height, weight, and blood pressure. The program requires these measures to be collected at the beginning of a formal screening cycle, regardless of the services being delivered. It is required that an average of two individual blood pressures be recorded. Failure to record the height, weight, and blood pressure of a participant will likely result in the screening record being excluded by the CDC as a viable record. The Med-IT® system will provide the averaged blood pressure and body mass index (BMI) when height (in inches), weight (in pounds) and two blood pressure measurements are recorded in the system. If the averaged blood pressure exceeds 180 mmHg (systolic) or 110 mmHg (diastolic), the participant MUST be referred for immediate medical care and the referral documented in the alert value follow-up section.

Clinical Breast Exam: A clinical breast exam is a screening test that may start a screening cycle and should be conducted within a 3 month window of the screening mammogram for those age-eligible. CDC allows for the following four outcome categories to be recorded as a result of the CBE. These

categories are **not** intended for use in clinical data collection but are required to be recorded as an indicator of the need for additional procedures. For more detailed on how to categorize clinical outcome into the codes below, please see the model clinical categories for CBE findings in [Appendix A](#).

- **Normal/Benign findings - schedule for routine CBE in one year:** If the result of the CBE is not suspicious for cancer, code the result as a “Normal/Benign,” regardless of the time until the next routine CBE. For example, if the CBE result is benign, but a CBE is recommended in six months instead of one year, still code the result as a “Normal/Benign.”
- **Abnormality suspicious for cancer - diagnostic evaluation needed:** An abnormal CBE suspicious for cancer, regardless of the initial mammogram findings, requires additional work-up and should have the Additional Breast Procedures Section of the MDEs completed.
- **Not needed:** If the participant has had a recent normal CBE and a breast exam is not necessary during this screening visit, code the result as “not needed.”
- **Needed, but not performed at this visit (includes refused):** If the provider indicates that a CBE is necessary during this screening visit, but is not provided, code “Needed, not performed.” This would include scenarios where (a) the participant refused to have the CBE performed, or (b) a trained CBE professional was not available to perform the exam.

Initial Mammogram: Unless a participant is being referred into the program for diagnostic evaluation of a previous abnormal screening test result, the initial mammogram should be entered in this section, whether a bilateral screening type (G0202) or a diagnostic screening type (G0204). The results of the mammogram are to be recorded as a Breast Imaging-Reporting and Data Systems (BI-RADS) score.

- **BI-RADS 0** = Assessment is incomplete - Need additional imaging evaluation
- **BI-RADS 0** = Assessment is incomplete – Film Comparison Required
- **BI-RADS 1** = Negative
- **BI-RADS 2** = Benign finding
- **BI-RADS 3** = Probably benign – Initial short interval follow-up suggested
- **BI-RADS 4**= Suspicious abnormality - biopsy should be considered
- **BI-RADS 5** = Highly suggestive of malignancy - Appropriate action should be taken
- **Result Unknown - Presumed Abnormal** = Non-program mammogram result could not be obtained prior to being referred in for diagnostic work-up. Using this category should be a rare occurrence as attempts should be made to obtain non-program results to substantiate the need for expending program funds on diagnostic services.
- **Unsatisfactory** - This category applies if the mammogram was technically unsatisfactory and could not be interpreted by radiologist. This result is different from an assessment incomplete (BI-RADS 0). A result of unsatisfactory indicates the screening cycle should be considered complete and a new screening cycle will begin with a repeat mammogram.

These categories are from the American College of Radiology (ACR) Breast Imaging Reporting and Database System. Please visit the ACR Web site (www.acr.org) for details on the latest lexicon.

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For the purpose of this Program, an **initial mammogram** is the first mammogram of a screening cycle. The initial mammogram may be billed as either a screening mammogram or a diagnostic mammogram. A diagnostic mammogram may be an initial mammogram when the client is considered symptomatic or has an abnormal CBE and this is the first mammogram for the cycle.

A response of “**Probably Benign**” (BI-RADS 3) should not be reported as the initial mammogram result unless a complete diagnostic work-up was performed (either within or outside of the program) prior to the current cycle. For example, if this is the first mammogram ever, for the participant, a response of BI-RADS 3 cannot be reported. The mammogram should be coded as a BI-RADS-4, BI-RADS 5 or BI-RADS 0 and additional breast procedures such as an ultrasound or additional mammographic views should be performed to rule out cancer. Once this participant receives diagnostic testing and a final diagnosis is obtained, any subsequent mammographic film in subsequent screening visits can be coded as BI-RADS 3.

A response of “**Assessment is Incomplete**” (BI-RADS 0) is used to represent those instances where the radiologic assessment is incomplete if, for example, magnification or additional views are needed to determine a final interpretation of the mammogram films.

A response of “**Unsatisfactory**” indicates that the cycle should be considered complete, and a new cycle will begin with a repeat mammogram. It is important for Programs to monitor the use of Unsatisfactory to determine if cycles are being reported appropriately.

A response of “**Presumed abnormal**” means that the actual mammogram result cannot be obtained for a patient who received their mammogram outside of the Program and was referred in to the Program for diagnostic work-up. The result is presumed abnormal; otherwise a diagnostic work-up would not be performed. This code should be limited to only those mammogram results that cannot be obtained and should be a rare occurrence. If the actual result from the outside mammogram is known, it should be reported.

A response of “**Needs Film Comparison**” means that the assessment of the initial mammogram is incomplete and the radiologist will require a review of previous mammographic films to make a final interpretation.

Dense Breast Ultrasound: CT law requires insurance companies to cover the cost of an ultrasound if the radiologist recommends such because the density of breast tissue is over 50% and may be preventing an adequate interpretation of the mammogram. Federal funds cannot be used to cover the cost of an ultrasound as a screening tool. It is important to document if the radiologist is recommending a dense breast ultrasound and record this in the system so the procedure can be reimbursed with state funds only.

Pap and HPV Tests: CDC does not consider a pelvic exam to be a cancer screening test, however, the outcome of the exam may be captured for clinical background. It is important to note if the cervix is present or if the participant is post-menopausal. The Pap test is what starts a cervical cancer screening cycle. The date of the Pap test and HPV test is recorded as the date that the sample was taken. The result of the Pap test is to be recorded in Bethesda 2001 terminology. CDC provides the following listing

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of Bethesda terminology to be used. If the Pap test outcome is ASC-US/+HPV, ASC-H, HSIL, SCC, or AGC, additional cervical procedures MUST be completed and a final diagnosis from all procedures is to be determined and recorded.

A Pap test is always a screening test, not a diagnostic test. Thus a Pap test should not appear under "Other" for diagnostic work-up for an abnormal Pap test. Post hysterectomy vaginal smears are appropriate to perform, and to report as a Pap test, as long as the hysterectomy was performed due to a cervical cancer or CIN. Results for these types of smears should use the same Bethesda categories as Pap tests. Vaginal smears should NOT have a result of VIN or VAIN, as these results can only be obtained through a biopsy diagnosis.

- **Negative for intraepithelial lesion or malignancy (NIL)** A response of Negative is used to indicate that there is no cellular evidence of neoplasia, whether or not there are any organisms or other non-neoplastic findings such as reactive changes, inflammation or atrophy. Cervicitis and chronic cervicitis are inflammatory responses considered "Normal" when it comes to reporting the outcome of cancer screening.
- **Atypical squamous cells of undetermined significance (ASC-US) :**
- **Low grade SIL (including HPV/mild dysplasia/CIN 1)**
- **Atypical squamous cells cannot exclude HSIL (ASC-H)**
- **High grade SIL (HSIL)**
- **Squamous Cell Carcinoma (SCC)**
- **Abnormal Glandular Cells (AGC)** (including Atypical, Endocervical Adenocarcinoma in situ and Adenocarcinoma) A response of 7 (AGC) may be used to indicate Atypical endocervical cells (NOS), Atypical endometrial cells (NOS), Atypical glandular cells (NOS), Atypical Endocervical or Glandular cells favoring neoplastic, Endocervical adenocarcinoma in situ and
- **Other:** this category is to be used ONLY if the outcome cannot be identified in any of the other Bethesda outcome.

If the Specimen Adequacy is Satisfactory, then there should be Bethesda 2001 findings provided in the cytology report and an appropriate Pap test result needs to be provided. Programs should contact the lab and request a Bethesda result if one was not made available. A response of "Other" should be used only if the cytology report was deemed satisfactory and indicates a result that is not a valid Bethesda result. Provide the result in **Other Pap Test Result**. Be careful regarding what is coded in "Other", as these results are difficult to use for analysis. Results such as "No Endocervical Cells", "No Endocervical Component" or "Lack of Endocervical Cells" are not appropriate "Other" Pap test results and should not be recorded as such.

If the Specimen Adequacy was found to be satisfactory, and a Bethesda 2001 result provided, then the Pap test result should reflect the Bethesda classification, even when notations state "No Endocervical Cells", "No Endocervical Component" or "Lack of Endocervical Cells." If the HPV test was also positive and the participant needs to return for rescreening in 1 year, a short-term follow-up date may be entered in the Med-IT "Due Date" section to remind providers of the next visit. There are currently no provisions for submitting a lack of endocervical cells to the CDC as a test outcome.

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If the Specimen Adequacy was found to be Unsatisfactory, even if due to “No Endocervical Cells”, “No Endocervical Component” or “Lack of Endocervical Cells” then the Pap test result should be left blank. There were insufficient cervical cells present for a reasonable evaluation of the material and a repeat Pap test should be performed within 2-4 months, and a new screening cycle record initiated for the results.

Pelvic Exam findings should not be reported as Other Pap test results. It is not necessary to indicate pelvic exam findings in order to validate the need for diagnostic work-up. It is important to collect this information for Program purposes, but pelvic exam findings should not be reported in the MDEs.

HD Screening Work-Up refers to the results of blood testing for cholesterol and glucose levels. The date of the blood test is the date the sample was taken and not the date of the results. CDC requires differentiation between a fasting result and a non-fasting result. When using the customized **Screening*CT** window in the Med-IT® system, blood work (screening work-up) results are required to be entered at the time the initial record is created. If you are adding blood work (screening work-up) results to an existing record in the Med-IT® system, you must use the standard Screening Work-Up window to enter your supplemental information.

Cholesterol Fasting Status

- **Yes**, the participant has fasted for at least nine hours prior to having blood test;
- **No**, the participant did not fast for at least nine hours prior to having blood test
- **No cholesterol measurements were available**, because either the blood sample was inadequate, or values could not be obtained due to technical difficulties
- **Don't know**, if the participant is not sure they fasted for at least 9 hours prior to having blood test.
- **Refused**, the participant refuses blood work (If a participant refuses to go to the lab, the participant can be considered to have refused blood work)
- **No answer**, if provider failed to confirm the fasting status

Total cholesterol measurements may be taken as fasting or non-fasting. At a minimum, every participant must have a total cholesterol and HDL cholesterol value recorded. If the participant was fasting and had a lipid panel completed at the baseline or rescreening visit, then LDL and triglyceride values should also be recorded in addition to total and HDL cholesterol.

Glucose Fasting Status

- **Yes**, the participant has fasted for at least nine hours prior to having blood test;
- **No**, the participant did not fast for at least nine hours prior to having blood test
- **No cholesterol measurements were available**, because either the blood sample was inadequate, or values could not be obtained due to technical difficulties
- **Don't know**, if the participant is not sure they fasted for at least 9 hours prior to having blood test.

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- **Refused**, the participant refuses blood work (If a participant refuses to go to the lab, the participant can be considered to have refused blood work)
- **No answer**, if provider failed to confirm the fasting status
- ***diabetic participant**, previously diagnosed with diabetes and will receive A1C test

*The Med-IT system will automatically deduce if the participant is diabetic and requires the A1C instead of a blood glucose test

Total Blood Glucose measurements are preferred to be taken as fasting but may be taken as non-fasting. In cases where the Cholestech machine indicates a reading of less than 50 mg/dL, the guidance is to code the participant's glucose as 50. This is considered an alert reading and participants should be seen immediately for medical follow-up. Diabetic participants should not have a blood glucose test. For these participants, providers are to use an A1C measurement, which provides information used to monitor the control of diabetes. Diabetic participants would have answer yes to question 3 and or question 10 of the heart Health Assessment Questionnaire.

DIAGNOSTIC FOLLOW-UP TO ABNORMAL BLOOD TEST

If a participant has a non-fasting abnormal screening value for a total cholesterol, HDL and/or glucose at the baseline screening or rescreening office visit, she should return for a repeat fasting lipid profile and glucose test on a separate occasion to accurately diagnose the condition(s). These tests can be performed by venipuncture or fingerstick methods. If the repeat fasting test results are abnormal, the woman should be referred to an existing medical care system for medical evaluation and treatment. No further blood tests are reimbursed by the program. Repeated blood test results can be written on the Screening and Assessment form next to the original values. For entry into Med-IT® the user will need to open the "Screening Work-Up" section of the system to enter a second set of results.

Alert Value Follow-Up is required to be documented. This is the date the participant was seen by a health care professional in regards to the alert value detected during screening. The policy for responding to alert values can be found in the Policy and Procedures Manual; Section II; Direct Services, and is included in **Appendix B** for your use. The Med-IT® system will also allow for you to document the outcome of follow-up, as this is a required MDE.

For participants with an alert value who were not seen within seven days of the date of their measurement, programs should submit a written explanation to the DPH Program Coordinator related to efforts for securing timely referrals as this information must be submitted to the CDC as a formal written response with each biannual data submission. Refer to the Alert Value Policy in **Appendix D**.

Cardiovascular Health Assessment (also known as **Heart Health Assessment Questionnaire**) is to be delivered only to female participants ≥ 40 years of age who are engaging in the breast and cervical cancer screening activities and who are receiving screening for the modifiable risk factors of heart disease. The "assessment" contains four sections; Heart Health, Physical Activity Readiness, Physical Activity, Nutrition, and a Readiness-To-Change score. Each of the heart health assessment questions requires an answer. Failure to record these answers will likely result in the record being excluded by the

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CDC as a viable screening record. Providers may choose to separate this Screening and Assessment page and send it along to the participant for completion before an integrated office visit is conducted. Before a participant can receive risk reduction counseling for increasing physical activity, a physical activity readiness assessment must be completed. If any of the answers are YES, the participant must be referred for and receive a clearance from their primary care provider before risk reduction counseling on physical activity can take place. This section allows for that documentation.

CRC Screening Procedure: Once a participant has been scheduled for a screening colonoscopy, adherence to the appointment is required to be recorded. The CRC Screening procedure sheet can be removed from the packet if no colonoscopy was scheduled.

When a colonoscopy has been scheduled from the eligibility assessment, , the screening exam date is the date of the scheduled colonoscopy. While other federal ly funded programs include Fecal Occult Blood Testing, the CT program provides only the colonoscopy as a reimbursable screening test. However, the data that the test is a colonoscopy must be recorded for the CDC.

The CCRCP is designed to screen individuals who are at average risk and have not received a colonoscopy within the last 10 years. The first test provided in the screening cycle should be recorded as a screening procedure. Surveillance colonoscopies are typically not reimbursable with program funds.

CDC defines CRC testing procedures as follows:

- A **screening test** 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** 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. Surveillance colonoscopies are typically not reimbursable with program funds.
- A **diagnostic test** is a test (typically a DCBE or colonoscopy) performed to evaluate signs or symptoms or to follow-up an abnormal screening test. THE CCHDIHSP does not fund diagnostic testing.

The name of the Provider performing the colonoscopy is to be recorded and the **Provider Specialty** must be recorded as one of the following choices:

- 1 = General practitioner
- 2 = Internist
- 3 = Family practitioner
- 4 = Gastroenterologist
- 5 = General surgeon
- 6 = Colorectal surgeon
- 7 = Other/Unknown

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Consultation Comments and the date of a consultation may be obtained during the health evaluation and can be recorded in the Med-IT system for future reference.

Outcome Summary: CDC requires specific information on the outcome of the colonoscopy. Providers are required to document if the bowel preparation was adequate; if the cecum was reached, and if and how many specimens were taken. If the preparation was deemed inadequate and/or the cecum was not reached, the procedure should be considered incomplete and repeated.

Document if any biopsies were performed and document if any polyps were removed. Document the number of specimens sent for pathology and document if the pathology report was received.

Documentation is required for complications during the procedure. Yes or no answers can be entered into the Med-IT system in the Screening and Diagnostic page and if the answer is yes, the specifics of the complication can be entered into the Med-IT system on the Final Diagnosis and Treatment page when concluding on the final outcome of all procedures. CDC expects complications to be recorded as follows:

Complications:

- No complications reported
- Bleeding requiring transfusion
- Bleeding not requiring transfusion
- Cardiopulmonary events (hypotension, hypoxia, arrhythmia, etc.)
- Complications related to anesthesia
- Bowel perforation
- Post-polypectomy syndrome/excessive abdominal pain
- Death
- Other (to be used when the previous cases do not apply and is to be recorded with a free text description of the complication)

Providers 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. Each of the two worst complications should be reported separately.

Test Outcome and Recommendations: Each test provided should have a specific result that is reported. If there were circumstances that prevented the first test from being performed satisfactorily such as an obstruction, inadequate bowel prep, or the cecum was not reached during colonoscopy, then the result should be reported as Incomplete/Inadequate. 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, the test would also be reported as 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 “Complete” and a final diagnosis determined. If, after the final diagnosis was complete and the recommendation is to repeat the colonoscopy in 3-6 months, then that procedure would begin a new cycle where the indication for the colonoscopy test would be a “surveillance” test. Remember, CCRCP

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funds are extremely limited and surveillance colonoscopies are typically not reimbursable with program funds. It's important to determine if the removal of polyps was complete enough to determine a final diagnosis or not complete enough to determine a final diagnosis. This criterion is the difference between repeating the procedure within the same screening cycle or completing the screening cycle with a final diagnosis and beginning another, unfunded colonoscopy for the purpose of surveillance.

Total Polyps: CDC requires an assessment and documentation of the largest polyp, the most severe histology of a polyp or lesion, and the total number of polyps or lesions that were found to be adenomatous or cancerous. The Med-IT system allows for documentation of each specimen extracted and whether that specimen was a full polyp, the biopsy of a polyp, or the biopsy of another type of lesion. CT requires that data on each specimen be recorded individually.

A table was designed by the CDC to assist providers in mapping specific ICD-O morphology codes into the following CCDE Histology codes and is provided in [Appendix C](#)

CRC Histology:

- Normal or other non-polyp histology - **Norm**
- Non-adenomatous polyp (inflammatory, hamartomatous, etc.) - **NonAd**
- Hyperplastic polyp - **Hyper**
- Adenoma, NOS (no high-grade dysplasia noted) - **AdNOS**
- Adenoma, tubular (no high-grade dysplasia noted) - **AdTub**
- Adenoma, mixed tubular villous (no high-grade dysplasia noted) - **Admix**
- Adenoma, villous (no high-grade dysplasia noted) - **Advill**
- Adenoma, serrated (no high-grade dysplasia noted) - **Adserr**
- Adenoma with high-grade dysplasia (includes in situ carcinoma) - **Addysp**
- Adenocarcinoma, invasive - **AdCanc**
- Cancer, other – **Canc**
- Unknown

CRC Location Choices:

- Rectum - **Rect**
- Rectum/Sigmoid Colon - **RecSig**
- Sigmoid Colon - **Sig**
- Descending Colon - **Desc**
- Left Colic (Splenic) Flexure - **Sple**
- Transverse Mesocolon - **Trans**
- Right Colic (Hepatic) Flexure - **Hep**
- Ascending Colon - **Asc**
- Cecum - **Cec**
- Appendix - **App**
- Overlapping Lesions - **OverLap**
- Unknown

Surgery Summary: If a surgical resection was performed during the colonoscopy procedure, CDC requires documentation of the worst histopathology from that resection and the date the resection was performed. If no surgical resection was performed, this section can be left blank.

Pathology Summary: In this section you will summarize and documentation of the largest polyp, the most severe histology of a polyp or lesion, and the total number of polyps or lesions that were found to

be adenomatous or cancerous. This data can be entered into Med-IT on the Final Diagnosis and Treatment screen.

Final Diagnosis: After the completion of the first screening colonoscopy and any additional procedures that are required to determine a final outcome, a final outcome/diagnosis is required to be recorded for the screening cycle. This is slightly different than when recording the final outcome of a normal breast cancer or cervical cancer screening test. If complication occurred during any of the tests, that data was collected in the test outcome summary and needs to be recorded in the Med-IT® system on the Final Diagnosis Screen. Providers 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. Each of the two worst complications should be reported separately. A table was designed by the CDC to assist providers in mapping specific ICD-O morphology codes into the following CCDE Histology codes and is provided in **Appendix C**

Complications:

- No complications reported
- Bleeding requiring transfusion
- Bleeding not requiring transfusion
- Cardiopulmonary events (hypotension, hypoxia, arrhythmia, etc.)
- Complications related to anesthesia
- Bowel perforation
- Post-polypectomy syndrome/excessive abdominal pain
- Death
- Other (to be used when the previous cases do not apply and is to be recorded with a free text description of the complication)

Future Screening Services: Based on outcome of the colorectal cancer screening services provided through the program (including any diagnostic or surgical work-up) a recommendation needs to be made as to when the participant should return to a clinician for additional services and what services should be delivered.

The type of test to be delivered to the client is defined by the CDC as the following:

- A **screening test** 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 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.

The recommended interval for future screening or surveillance testing is provided in guidance published by the American Gastroenterological Association. That guidance can be found at www.gastro.org, and is

provided below. Remember, CCRCF funds are extremely limited and surveillance colonoscopies are typically not reimbursable with program funds. It's important to determine if the removal of polyps was complete enough to determine a final diagnosis or not complete enough to determine a final diagnosis. This criterion is the difference between repeating the procedure within the same screening cycle or completing the screening cycle with a final diagnosis and beginning another, unfunded colonoscopy for the purpose of surveillance.

Guidelines for Colonoscopy Surveillance After Screening and Polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer, DAVID A. LIEBERMAN,* DOUGLAS K. REX, SIDNEY J. WINAWER, FRANCIS M. GIARDIELLO, DAVID A. JOHNSON, and THEODORE R. LEVIN; GASTROENTEROLOGY 2012;143:844–857

Table 1. 2012 Recommendations for Surveillance and Screening Intervals in Individuals With Baseline Average Risk

Baseline colonoscopy: most advanced finding(s)	Recommended surveillance interval (y)	Quality of evidence supporting the recommendation	New evidence stronger than 2006
No polyps	10	Moderate	Yes
Small (<10 mm) hyperplastic polyps in rectum or sigmoid	10	Moderate	No
1–2 small (<10 mm) tubular adenomas	5–10	Moderate	Yes
3–10 tubular adenomas	3	Moderate	Yes
>10 adenomas	<3	Moderate	No
One or more tubular adenomas ≥10 mm	3	High	Yes
One or more villous adenomas	3	Moderate	Yes
Adenoma with HGD	3	Moderate	No
Serrated lesions			
Sessile serrated polyp(s) <10 mm with no dysplasia	5	Low	NA
Sessile serrated polyp(s) ≥10 mm	3	Low	NA
OR			
Sessile serrated polyp with dysplasia			
OR			
Traditional serrated adenoma			
Serrated polyposis syndrome ^a	1	Moderate	NA

NOTE. The recommendations assume that the baseline colonoscopy was complete and adequate and that all visible polyps were completely removed.

NA, not applicable.

^aBased on the World Health Organization definition of serrated polyposis syndrome, with one of the following criteria: (1) at least 5 serrated polyps proximal to sigmoid, with 2 or more ≥10 mm; (2) any serrated polyps proximal to sigmoid with family history of serrated polyposis syndrome; and (3) >20 serrated polyps of any size throughout the colon.

Treatment - Cancer Type: If colorectal cancer is detected, it is required to document progress toward treatment. Providers will need to work with their subcontractors to determine if the cancer is a new primary colorectal cancer or if the cancer is a metastasis of a non-colorectal primary site. The choice “Unknown” might be reported if cells are so poorly differentiated that the organ of origin cannot be identified. The response of unknown should occur rarely.

Treatment - Status: 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 Treatment Started. In the event that the client chooses a form of non-standard or alternative treatment, this field should be coded as Treatment refused. NOTE: Experimental drugs, such as those used in clinical trials, may be reported as 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 provider 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, Treatment should be reported "Treatment not indicated due to polypectomy", and Date of Treatment will be the day of the polypectomy. In this instance "Date" of final diagnosis and "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 Date of Surgery, the Treatment should be "Treatment not indicated due to polypectomy", and 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.

- Treatment started and/or completed
- Treatment pending
- Treatment not indicated due to polypectomy
- Treatment not recommended
- Treatment refused
- Lost to follow-up
- Unknown

Risk Reduction Form

Risk Reduction Status: Risk Reduction Counseling (RRC) is required for every woman screened for CVD modifiable risk factors. Providers are required to document the components of the risk reduction program that were delivered to each participant. All women are required to receive their results both verbally and in writing and should receive a copy of results in the *My Heart Health Screening Results* document and a copy of the site's *Community Resources and Lifestyle Programs Guide*. The RRC counselor should review the guide with the patient and help the woman find one or two places that can support her goals. Referrals to community resources must be documented in the first section of the form and should be specific. Community resources are a major area of focus in the new grant and we should be prepared to ensure all women are referred to area resources.

Lifestyle Goals: During risk reduction activities, participants are encouraged to develop goals for implementing certain changes in their lifestyle that can lead to a lower risk for heart disease. Providers are required to document electronically any of these goals were set and to provide details on what they are. Initial goals set during RRC are discussed during the first and subsequent LSI sessions provided by the DPH Lifestyle Interventionist.

Goals listed should be specific, measurable, and reasonable. RRC counselors are to work with women to tease out specific goals. Instead of "I will eat more fruits and vegetables" or "I will exercise more" try

to get a specific amount – “I will eat at least one extra serving of fruit and one extra serving of vegetables each day” or “I will walk one extra day each week.” Examples of goal setting are available on the *My Heart Health Screening Results* document.

It is expected that women who have a nutrition goal will have a resource for nutrition; those that have a physical activity goal will have a resource listed for physical activity; and, those that have a smoking cessation goal will have one or more resources listed for smoking cessation.

Client’s Confidence of Success Score: The client’s confidence score of success provides an indication of how committed and thus how likely a participant will continue to work on their goals. This score is collected at the risk reduction visit and all proceeding LSIs. Providers are required to capture this information electronically.

Breast and Cervical Cancer Diagnosis Treatment Form

BREAST CANCER DIAGNOSTIC FOLLOW-UP

Diagnostic services for detecting breast cancer can be offered through the program under four scenarios and are often required services to reach a final diagnosis from an abnormal screening test result that was provided through the program. Clinical scenarios requiring diagnostic follow-up include the following.

An Abnormal Clinical Breast Exam

This is not an accounting of the symptoms reported to the clinician about the breast, but the actual findings of a clinical breast exam as performed by the clinician during the screening visit. Providers are not to refer a client directly to a breast specialist without first verifying self-reported claims of symptoms suspicious for cancer. An abnormal CBE that is suspicious for cancer, regardless of the initial mammogram findings, requires additional work-up and should have the additional breast procedures section completed. *[For the purpose of this Program, an initial mammogram is the first mammogram of a screening cycle. The initial mammogram may be billed as either a screening mammogram or a diagnostic mammogram. A diagnostic mammogram may be an initial mammogram when the client is considered symptomatic or has an abnormal CBE and this is the first mammogram for the cycle.]* In other words, when the CBE is suspicious for cancer, even if the bilateral diagnostic mammogram conducted as the initial screening mammogram had an outcome of BIRADS 1, additional work-up should be completed.

At the request of the Programs, and to propose a model for the collection of the CBE data at the clinical level, categories were proposed by a working group of the CDC and Program participants in the spring of 1994. The use of these clinical categories on data collection tools is strongly recommended.

The CBE result of “Abnormality suspicious for Cancer – diagnostic evaluation needed” include CBE outcome of:

- Discrete palpable mass (includes masses that may be cystic or solid, as well as indistinct palpable masses)
- Bloody or serous nipple discharge
- Nipple or areolar scaliness
- Skin dimpling or retraction

Note: “Discrete palpable mass – previously diagnosed as benign” is considered a “Normal/Benign” finding. Please see the model clinical categories for CBE findings in [Appendix A](#) for further details.

An Abnormal Or Incomplete Mammogram:

Additional Procedures needed to complete a Breast Cancer Screening Cycle are necessary for initial mammogram results of:

- Suspicious abnormality - biopsy should be considered (BI-RADS 4)
- Highly suggestive of malignancy - Appropriate action should be taken (BI-RADS 5)
- Assessment is incomplete - Need additional imaging evaluation (BI-RADS 0)
- Result unknown, presumed abnormal, mammogram from non-program funded source and no results obtainable
- Film comparison required (BI-RADS 0).

To take the confusion out of which services require additional procedures needed to complete a final diagnosis, the CDC created a Minimum Data Element called “Additional Procedures Needed to Complete Breast Cycle.” If the CBE was considered to be an abnormality suspicious for cancer or if the mammogram result was determined as BIRADS 0, BIRADS 4, BIRADS 5, or Unknown, additional work-up is required and the electronic record in Med-IT® is coded to reflect such. Running the “Follow-Up” Report in Med-IT® will identify cases where abnormal screening results are missing documentation of diagnostic follow-up.

Short term diagnostic follow-up:

Participants who were previously screened and found to have an abnormality that requires additional services sooner than a recommended screening interval, are often eligible for additional diagnostic work-up as a short-term diagnostic follow-up. This situation is most commonly seen when mammography results are determined as BIRADS 3. The participant will often be requested to return to the radiologist in 6 months for a unilateral diagnostic mammogram of the previously detected abnormality in question. In this case, the indication of the 6 month screening cycle would be “**Initial mammogram not done, patient received only CBE or proceeded directly for other imaging or diagnostic work.**” The 6-month diagnostic mammogram would be recorded as a diagnostic imaging procedure and a final diagnosis determined. This course of action can put the participant back on track for their annual screening services.

Referred in with previous abnormal:

Participant who receive their CBE and/or screening mammogram from an outside provider can be referred into the program for diagnostic follow-up with the results of that outside test. The criteria for

diagnostic work-up are similar to having the screening test done in the program. Refer to the above for an Abnormal Clinical Breast Exam or An Abnormal Or Incomplete Mammogram. In the rare case when results from the non-program test cannot be obtained, record the date of the procedure to as close as what can be remembered and record the outcome of the procedure as Result Unknown-Presumed Abnormal.

Types of Breast Cancer Diagnostic Follow-up:

Providers are required to differentiate between diagnostic follow-up that is needed to reach an imaging conclusion and that which is needed to obtain a pathological specimen.

Additional Breast Imaging Procedures

Additional breast imaging procedures may be needed to resolve the interpretation of the screening mammogram or as a diagnostic procedure in response to a CBE abnormality suspicious for breast cancer. The additional imaging section is used for the reporting of compression views, cone compression, magnification views and diagnostic mammograms that are not considered the initial screening mammogram. If the initial screening mammogram was a diagnostic mammogram, then it should not be reported in this section, but should be reported as the initial screening mammogram. Additional imaging procedures may be recorded as

- Film Comparison
- Unilateral Diagnostic Mammogram (Conventional)
- Unilateral Diagnostic Mammogram (Digital)
- Bilateral Diagnostic Mammogram (Conventional)
- Bilateral Diagnostic Mammogram (Digital)
- Breast Ultrasound or Sonography

Ductograms or Galactograms are procedures performed in conjunction with a mammogram to *support* the result of that procedure and are not reimbursable with Program funds. These procedures may be collected in the Med-IT® data collection system to show the full scope of services provided, but will not be submitted as part of the CDC record. If these procedures are reported as being the only diagnostic test provided to a participant, a case manager should review the case more thoroughly.

If ultrasound imaging is performed more than once for a participant during separate visits in the same screening cycle to obtain a final imaging outcome, it is only necessary to complete this item once. Ultrasound imaging is not the same as imaging guidance and should not be used in conjunction with clip or needle placement.

Final Imaging Outcome

The outcome of any additional imaging procedures must be recorded as a BI-RADS classification and a final imaging outcome recorded separately from the final diagnosis. (Read more in Final Diagnosis and Treatment section.)

Additional Breast Diagnostic Procedures:

Are typically non-imaging procedures designed to confirm the suspicions of a potentially cancerous lesion. The CDC provides categories for breast diagnostic procedures that need to be reported upon individually. It is not appropriate to include any of these procedures in the category of “Other” when reporting additional diagnostic procedures.

- Repeat Breast Exam / Surgical Consultation is used for reporting if a second opinion, surgical consult and/or repeat clinical breast exam was performed by a breast specialist. A breast specialist is a clinician who identifies him/herself as an expert in breast health. This may be a breast surgeon, radiologist, oncologist, etc. Providers may choose to separate information about surgical consultations and repeat breast exams in their data management system, but both will collapse into the same response. If more than one surgical consultation or repeat breast exam is performed for a participant during separate visits in the same cycle to obtain a final diagnosis, it is only necessary to complete this item ONE TIME, and it may only be allowed to be reimbursed one time.
- Biopsy/Lumpectomy is used for reporting if a biopsy or lumpectomy was performed. If more than one biopsy is performed in the same cycle for a participant during separate visits to obtain a final diagnosis, then it is only necessary to complete this item once as 1 (Yes) in the MDE file. A lumpectomy intended as a treatment procedure should not be reported in this item. However, in some cases an excisional biopsy is performed and upon pathological review it is determined that the margin of the tumor falls completely within the biopsy specimen. As a result, the biopsy intended to be a diagnostic procedure also serves as treatment (lumpectomy). Such a procedure can be reported as a diagnostic procedure, as would an incisional biopsy or core needle biopsy. Supportive procedures such as stereotactic localization, or image guidance are performed in conjunction with a biopsy. In these instances, the only procedure necessary to report is the actual biopsy. Please do not report the supportive procedures in “Other Breast Procedures Performed” category.

For the purposed of reimbursement, the Med-IT system collects data on the specific CPT code procedure for the biopsy/lumpectomy. The following breast biopsy/lumpectomy procedures and CPT codes are currently programmed into Med-IT®:

19100	Breast biopsy, percutaneous, needle core, not using imaging guidance
19101	Breast biopsy, open, incisional
19102	Breast biopsy, percutaneous, needle core, using imaging guidance; <i>for placement of localization clip use 19295</i>
19103	Breast biopsy, percutaneous, automated vacuum assisted or rotating biopsy device, using imaging guidance
19120	Excision of cyst, fibroadenoma or other benign or malignant tumor, aberrant breast tissue, duct lesion, nipple or areolar lesion; open; one or more lesions
19125	Excision of breast lesion identified by preoperative placement of radiological marker; open; single lesion
19126	Excision of breast lesion identified by preoperative placement of radiological marker, open; <i>each additional lesion separately identified by a preoperative radiological marker</i>

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- Fine Needle / Cyst Aspiration is used for reporting if a fine needle or cyst aspiration was performed as a procedure to either detect, or to rule out cancer. Aspiration services that are delivered for reasons other than confirming or ruling out cancer, may not be reimbursed with program funds.

10021	Fine needle aspiration without imaging guidance
10022	Fine needle aspiration with imaging guidance
19000	Puncture aspiration of cyst of breast
19001	Puncture aspiration of cyst of breast, each additional cyst, <i>used with 19000</i>

CDC allows for documentation of breast cancer diagnostic procedures other than those identified above. However, if the procedure is not on the *Connecticut Allowable Procedures and Relevant CPT Codes* document, the procedure cannot be reimbursed with Program funds.

- Other Breast Procedures Performed is a category used to indicate if breast diagnostic procedures other than those specified above were performed to help determine a final diagnosis for a participant. Only diagnostic procedures which can provide a diagnosis of cancer or not cancer should be reported in this item. Examples include: Medical consultation (other than for repeat CBE), Skin biopsy, or Magnetic Resonance Imaging (MRI).

There are many procedures that can be performed in conjunction with those procedures specified above, that *support* the result of that procedure, but which are not a diagnostic procedure that *provides* a diagnosis. These types of procedures should not be reported as “Other Breast Procedures” and are not reimbursable with Program funds. These procedures may include: Ductogram or Galactogram, Nipple discharge cytology, Nuclear or Miraluma scan, or Computer-aided detection (CAD).

If these procedures are reported as the only diagnostic test provided to the participant, a case manager should review the case more thoroughly. This item should not be used for the reporting of definitive treatment procedures such as radical or simple mastectomy. In addition, procedures done to determine stage or to develop a treatment plan should also not be reported in this section. Examples of what should not be recorded as Other Breast Diagnostic Procedures include bone scans, CAT (Computed Axial Tomography) scans, chest X-rays, DEXA Scans, whole body scans, Prolactin level checks, and ultrasounds to rule out breast cancer metastases. A final diagnosis would have already been reached for the participant prior to ordering these types of procedures.

Final Breast Cancer Diagnosis

The “status” of Final Diagnosis/Imaging or Diagnostic Disposition is the status of the final outcome of all the tests provided during this screening cycle. The following choices are available to conclude the disposition of final diagnosis:

Work-up Complete: A status of 1 (Work-up Complete) indicates that the diagnostic testing is complete, and that the final diagnosis and date of final diagnosis are known. If a response of Work-up Complete is indicated, then at least one additional breast procedure (diagnostic or imaging) must have been performed, and a Final Diagnosis and Date of Final Diagnosis/Imaging must be completed.

Lost to Follow-up: A status of Lost to Follow-up should be reported if prior to the initiation or completion of diagnostic work-up a participant moves to a location beyond the Program's range of service delivery (e.g. to another country), or she cannot be located by the Program (e.g. moved). Lost to Follow-up should be reported when tracking efforts have been attempted in accordance with the Program's written protocol, but were unsuccessful. While such cases are simply reported to the CDC as "Lost", Providers should track more detailed information about each "lost" case to better manage their program's outcome. If a participant dies prior to the initiation or completion of diagnostic work-up, the status should also be indicated as Lost to Follow-up. For more information on determining Lost to Follow-Up review the **Lost to follow-Up Protocol** in the Policy and Procedure Manual Section II - Direct Services.

Work-up Refused: A status of Work-up Refused should be reported if a participant severs her relationship with the Program. For example, a participant may decline the recommended diagnostic work-up, or may choose to have the diagnostic work-up performed by a provider outside of the program.

***Irreconcilable: Note:** This choice is not available to Providers and should not be used in any circumstance. A status of "Irreconcilable" is available to administrative staff and 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 MDE data record. For example, a clinician might refer a participant for short-term follow-up instead of following the clinical guidelines for immediate diagnostic work-up. In such cases, DPH will enter "Irreconcilable" to indicate a cycle that has been reviewed and subsequently closed with an irreconcilable status. It is recommended by the CDC that Programs do not include irreconcilable status of final diagnosis on their data collection forms for providers to select. The intent of irreconcilable status of final diagnosis is for administrative use at the Program's central data location, and not at the provider level. Its intended use is to help Programs manage the records in the Audit 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. Final diagnosis is an important outcome measure for the CBCCEDP. Thus it is critical that these data are complete, timely, and accurate.

Final Diagnosis : This item should always be completed when Additional Procedures Needed to Complete Breast Cycle are performed and the Status of Final Diagnosis/Imaging is Work-up Complete. The classifications for a final breast cancer screening diagnosis are as follows:

- **Breast Cancer not diagnosed:** If a participant receives additional imaging procedures and the final imaging outcome is such that no further diagnostic procedures are required, then this item should be reported as Breast Cancer not diagnosed.

The term "invasive breast cancer" is meant to refer to histologic characteristics of tumors found primarily within the breast; most specifically, glandular tumors. However, there are occasions when the cancer may include connective tissue, etc. Melanoma is a skin- based cancer that can occur anywhere, and it should be reported as Breast Cancer Not Diagnosed. Lymphoma and leukemia are

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lymphatic and blood system cancers and they should also be reported as Breast Cancer Not Diagnosed.

- **Carcinoma In Situ, Other** (should not be used after 10/01/1999)
- **Lobular Carcinoma In Situ (LCIS)** - The CDC is aware that there are some rare instances where the Final Diagnosis may be both DCIS and LCIS. In these cases, the Final Diagnosis should be reported and treated as DCIS.
- **Ductal Carcinoma In Situ (DCIS)** - The CDC is aware that there are some rare instances where the Final Diagnosis may be both DCIS and LCIS. In these cases, the Final Diagnosis should be reported and treated as DCIS.
- **Invasive Breast Cancer:**

If multiple primary tumors are detected in one screening, then report the most serious diagnosis. For example, if a participant is diagnosed with both In Situ and invasive breast cancer, then report the invasive cancer as the final diagnosis.

Sarcomas that are generally considered to have primary origin in the breast may be reported as Invasive Breast Cancer. The program data set is a data set for the reporting of cancer incidence. Therefore, cancer recurrences should not be reported in its data set. In the event that a second diagnosis of breast cancer is reported for a participant, the Program should share the necessary information with its Cancer Registry to determine if the cancer is a new primary or a recurrence. If the breast cancer is determined to be a new primary, then it may be reported in the Program data file.

A Table was designed by the CDC to assist Providers in mapping specific ICD-9 morphology codes to the Final Diagnosis category. This table can be found in [Appendix C](#).

Date of Final Diagnosis: If the Status of Final Diagnosis/Imaging is Work-up Complete, Lost to Follow-up, Work-up Refused or Irreconcilable, then this item should be completed; otherwise this item should be left blank.

This item is for reporting of the date that the clinical diagnosis is made, or the date on which the clinical decision is made that no cancer is present. If the Status of Final Diagnosis/Imaging is Work-up Complete, then report the date of the diagnostic procedure that either confirmed the final diagnosis of cancer or the date that cancer was ruled out as the final diagnosis. If more than one procedure was performed, then use the date of the procedure that provided the definitive diagnosis. If the Status of Final Diagnosis is Lost to Follow-up, Work-up Refused or Irreconcilable, then the Date of Final Diagnosis/Imaging item must be completed with an administrative closeout date in alignment with Program policy. The date of final diagnosis that is reported for a lost to follow-up case should be the date that the policy guidelines are satisfied. This is the administrative closeout date for the record, and should not be interpreted as a cessation of attempts to have the participant return for appropriate care. The CDC realizes that in many cases attempts to contact a participant continue well beyond this administrative date. In the event that these efforts are successful and the participant returns to the Program, a new screening cycle should be started. If a participant dies before the diagnostic work-up is either started or completed, then enter the date of death as the administrative closeout date for this item. Similarly, each Program should have a policy that outlines the requirements for determining that a participant has refused follow-up services.

The date of final diagnosis that is reported for a “Refused” case should be the date that the policy guidelines are satisfied. The date of final diagnosis for records with a “Irreconcilable” status of final diagnosis should be the date on which the Program determines via internal review of a record that there was no sufficient way to translate the clinical scenario into a complete record, and that the record will remain incomplete. Program measures such as the time from screening to final diagnosis and time from final diagnosis to treatment initiation are calculated using this date.

Final Imaging Outcome

The purpose of this item is to report the assessment from all of the imaging procedures performed, including comparison with previous films, needed to arrive at a final outcome. Assessment Incomplete is not an option for this item. The final outcome of additional imaging procedures (the final outcome of the combination of all imaging procedures, screening and diagnostic) must be recorded separately from a final diagnosis and in addition to a final diagnosis from all screening tests and diagnostic procedures. This item should be completed when Additional Mammographic Views, Ultrasound and/or Film comparison to evaluate an Assessment Incomplete have been conducted. If no additional breast imaging procedures were performed, then this item should be left blank. The final imaging outcome must be reported as a BI-RADS classification. The following BI-RADS classification are acceptable:

- BI-RADS 1 = Negative
- BI-RADS 2 = Benign Finding
- BI-RADS 3 = Probably benign - Short interval follow-up indicated
- BI-RADS 4 = Suspicious Abnormality - Biopsy should be considered
- BI-RADS 5 = Highly Suggestive of Malignancy - Appropriate action should be taken

If at least one procedure was planned, but the patient refused the procedure, or was lost to follow-up prior to its completion, indicate this the Status of Final Diagnosis/Imaging as described above.

Final Imaging Outcome Date:

Report the date of the procedure that provided the final imaging outcome. If additional imaging is performed on more than one date, then report the date of the last procedure used to determine a final imaging outcome.

Breast Cancer Treatment

A status of Treatment Not Needed should be reported only in instances where the clinician and the participant jointly agree that treatment of the cancer would adversely affect the participant’s quality of life. This may occur, for example, in cases of late or end stage cancers. It is not appropriate to record that breast cancer treatment is not needed for cases where breast cancer is not diagnosed. It is not necessary to state that treatment is not needed for an outcome that does not require treatment.

Treatment Needed : It is up to the clinician to determine the course of action for a participant screened through this program and found to have breast cancer (Invasive Breast Cancer or Ductal Carcinoma In Situ). And this decision needs to be recorded in the participant’s Program record. No Program funds can be used for cancer treatment, however, participants diagnosed through the CBCCEDP are eligible for treatment services through Medicaid as specified in the CT Breast and Cervical Cancer Treatment Act. For more information about enrollment into Medicaid for breast cancer treatment see the **Procedure**

for Becoming a Qualified Entity (QE) and the W-1BCC Fast Form in the CCHDIHSP Policy Manual Section I Requirements and Guidance. In some instances, a diagnostic procedure may also constitute standard treatment. In such cases, the procedure should be reported as a breast diagnostic procedure. The Status of Final Diagnosis/Imaging should be reported as Work-up Complete; and a Final Diagnosis and Date of Final Diagnosis should be reported. The Status of Treatment should be Treatment Started, and the Date of Treatment Status should be the date of the procedure. In most of these instances, the Date of Final Diagnosis and the Date of Treatment Status will be the same.

Recommended Treatment: For the purpose of the CBCCEDP, CDC requires the reporting of standard or conventional treatments only. Note however that treatment using experimental drugs, such as those used in clinical trials, may be reported as Treatment Started.

A status of Treatment Refused should be reported in the event that a participant chooses a form of non-standard or alternative treatment.

The CDC conferred with Cancer Registry staff to obtain a list of standard treatment options for in situ and Invasive Breast Cancer and they are listed as follows:

- Mastectomy
- Lumpectomy; excisional biopsy
- Re-excision of the biopsy site
- Wedge resection
- Quadrantectomy
- Radiation Therapy
- Chemotherapy
- Hormonal Therapy (e.g. Tamoxifen)
- Immunotherapy (e.g. Herceptin)
- Bone Marrow Transplant
- Axillary lymph node dissection

Disposition or Status of Recommended Treatment:

The fact that a participant is referred for standard treatment is not sufficient confirmation that treatment has been started. A participant should be classified as having started treatment only after the Program has confirmed that a plan for standard treatment of the cancer has been developed and started. The following are categories for classifying the disposition of treatment:

Treatment Started: The Status of Treatment is an important outcome measure for the CBCCEDP. It is important to know the percentage of women diagnosed with breast cancer that have started treatment. Thus it is critical that these data are complete, timely, and accurate. A participant should be classified as having started treatment only after the Program has confirmed that a plan for standard treatment of the cancer has been developed and started. For the purpose of the NBCCEDP, CDC requires the reporting of standard or conventional treatments only. Note however that treatment using experimental drugs, such as those used in clinical trials, may be reported as Treatment Started.

Treatment Refused: A status of Treatment Refused should be reported if a participant severs her relationship with the Program following diagnosis but prior to the initiation of treatment; or in the event that a participant chooses a form of non-standard or alternative treatment. If a Participant is refusing treatment, it's important to document the reason why. This information can be entered into clinical notes and can also be entered into the final diagnosis screen of the Med-IT® system.

Lost to Follow-up: A status of Lost to Follow-up should be reported if following a diagnosis but prior to the initiation of treatment a participant moves to a location beyond the Program's range of treatment services (e.g. to another state or country), or she cannot be located (e.g. moved). Lost to Follow-up should be reported when tracking efforts have been attempted in accordance with the Program's written protocol, but were unsuccessful. While such cases are simply reported to the CDC as "Lost" Programs should track more detailed information about each case to aid in better management of Program outcome. If a participant dies prior to the initiation of treatment, the status should be reported as Lost to Follow-up.

Treatment Not Needed: A status of Treatment Not Needed should be reported in instances where the clinician and the participant jointly agree that treatment of the cancer would adversely affect the participant's quality of life. This may occur, for example, in cases of late or end stage cancers.

In cases where the diagnostic procedure is also therapeutic (treatment) the Status of Final Diagnosis/Imaging should be reported as Work-up Complete; and a Final Diagnosis and Date of Final Diagnosis should be reported.

The Status of Treatment should be Treatment Started, and the Date of Treatment Status should be the date of the procedure. In most of these instances, the Date of Final Diagnosis and the Date of Treatment Status will be the same.

Date of Disposition or Status of Recommended Treatment

If the Status of Treatment is Treatment Started, Lost to Follow-up, Refused, or Treatment Not Needed, then this item should be completed; otherwise this item should be left blank.

In some instances, a diagnostic procedure may also constitute standard treatment. In such cases, the procedure should be reported as a breast diagnostic procedure. The Status of Final Diagnosis/Imaging should be reported as Work-up Complete; and a Final Diagnosis and Date of Final Diagnosis should be reported. The Status of Treatment should be Treatment Started, and the Date of Treatment Status should be the date of the procedure. In most of these instances, the Date of Final Diagnosis and the Date of Treatment Status will be the same.

If the Status of Treatment is Treatment Started, then report the date on which the participant began standard treatment. If the Status of Treatment is Lost to follow-up, Treatment Refused or Treatment Not Needed, then the "Date of Treatment Status" item must be completed with an administrative closeout date. Each Program is expected to have a "Lost to Follow-up Policy" which outlines the number and types of attempts that the Program should make to contact a participant before she is declared Lost to Follow-up. The date of treatment status that is reported for a "Lost to Follow-up" case should be the date that the policy guidelines are satisfied. This is the administrative closeout date for the record. Also, if a participant dies before treatment is initiated, then enter the date of death as the administrative closeout date for this item. The CDC realizes that in many cases attempts to contact a participant continue well beyond this administrative date. In the event that these efforts are successful and the participant returns to the Program, a new screening cycle should be started. Similarly, each Program

should have a policy that outlines the requirements for determining that a participant has refused treatment. The date of treatment status that is reported for a "refused" case should be the date that the policy guidelines are satisfied. To review the CBCCEDP policies on Lost to Follow-Up and Refused Treatment refer to the **Lost to Follow-Up Protocol** in the Policy and Procedure Manual Section II - Direct Services.

CERVICAL CANCER DIAGNOSTIC FOLLOW-UP

Diagnostic services for detecting cervical dysplasia or cancer can be offered through the program under four scenarios and are often required services to reach a final diagnosis from an abnormal screening test result that was provided through the program. Clinical scenarios requiring diagnostic follow-up include the following.

An Abnormal Pap test and/or combination positive HPV Test:

Additional Procedures needed to complete the cervical cancer screening cycle are necessary for the initial cervical screening results of:

- **HSIL:** High grade Squamous Intraepithelial Lesions
- **Squamous Cell Cancer**
- Result unknown, presumed abnormal, Pap test from non-program funded source
- **AGC:** Abnormal Glandular Cells (including Atypical Glandular Cells of Undetermined Significance (AGUS) and Adenocarcinoma)

Additional procedures needed to complete the cervical cancer screening cycle may also be necessary for the initial cervical screening results of

- **ASC-US /+HPV:** Atypical Squamous Cells of Undetermined Significance and a positive Human Papillomavirus Test
- **ASC-H:** Atypical Squamous Cells Cannot Exclude High Grade Squamous Intraepithelial Lesions
- **LSIL:** Low Grade Squamous Intraepithelial Lesions

To take the confusion out of which services require additional procedures needed to complete a final diagnosis, the CDC created a Minimum Data Element called "Additional Procedures Needed to Complete Breast Cycle." If any of the scenarios above are true, additional work-up is required and the electronic record in Med-IT is coded to reflect such. Running the "Follow-Up Report in Med-IT® will identify cases where abnormal screening results are missing documentation of diagnostic follow-up.

Short term diagnostic follow-up:

Participants who were previously screened and found to have an abnormality that requires additional services sooner than a recommended screening interval, are often eligible for additional diagnostic work-up as a short-term diagnostic follow-up if the Pap test was performed for a participant under management for a cervical abnormality detected prior to this cycle. This situation is most commonly seen when the management of cervical cytological or histological abnormalities is to repeat cytology in 6 months. In this case, the indication of the 6 month screening cycle would be "**Patient under**

surveillance for a previous abnormal test”. The 6 month Pap test would be recorded as a screening Pap test and not as a diagnostic procedure.

Referred in with previous abnormal:

Participant who received their Pap test from outside of the Program can be referred into the program for diagnostic follow-up. The Cervical Diagnostic Referral Date must be completed, and a valid Pap test Result provided. In the rare case when results from the non-program test cannot be obtained, record the date of the procedure to as close to what can be remembered and record the outcome of the procedure as Result Unknown-Presumed Abnormal.

Additional Cervical Diagnostic Procedures:

Are designed to confirm the suspicions of a potentially cancerous cervical lesion. The CDC provides categories for cervical diagnostic procedures that need to be reported individually. It is not appropriate to include any of these procedures in the category of “Other” when reporting additional diagnostic procedures. An HPV test performed immediately following an ASC-US Pap test Result is not considered diagnostic work-up.

- **Colposcopy without Biopsy** (CPT code 57452) A Colposcopy without Biopsy and Colposcopy with Biopsy and/or ECC are mutually exclusive; both items should not be recorded in the same record. If both procedures were performed during a single screening cycle, code the more definitive procedure.
- **Colposcopy with Biopsy and/or ECC** Programs should indicate this procedure when any of the following occur:
 - Colposcopy + Biopsy (CPT code 57455)
 - Colposcopy + ECC (CPT code 57456)
 - Colposcopy + Biopsy + ECC (CPT code 57454)

Colposcopy without Biopsy and Colposcopy with Biopsy and/or ECC are mutually exclusive; both items should not be recorded in the same record. If both procedures were performed during a single screening cycle, code the more definitive procedure.

- **Loop Electrosurgical Excision Procedure (LEEP)** (CPT code 57522) Note: this is CPT 57522. This is not a Loop Electrode Biopsy (57460) nor a Loop Electrode Conization (57461). This item is used for the reporting of LEEP performed as a diagnostic procedure, and should not be used to report a LEEP performed strictly as treatment. However, if the LEEP was performed as both a diagnostic procedure and also served as a therapeutic procedure, the procedure would be recorded both here and in the cervical cancer treatment section as a treatment procedure.
- **Cold Knife Cone** (CPT code 57520) This item is used for the reporting of Cold Knife Cone performed as a diagnostic procedure, and should not be used to report Cold Knife Cone performed as treatment. However, if the CKC was performed as both a diagnostic procedure and also served as a therapeutic procedure, the procedure would be recorded both here and in the cervical cancer treatment section as a treatment procedure.

- **Endocervical Curettage alone (CPT Code 57505)** This item is used for the reporting of a stand-alone ECC. It should not be used to report ECC that is done in conjunction with colposcopy. ECC done in conjunction with a colposcopy should be reported as Colposcopy with Biopsy and/or ECC. A stand-alone ECC is an appropriate option for diagnostic work-up of a Pap Test result of AGC when endometrial cells are present.

CDC allows for documentation of cervical cancer diagnostic procedures other than those identified above. However, if the procedure is not on the *Connecticut Allowable Procedures and Relevant CPT Codes* document, the procedure cannot be reimbursed with Program funds.

- Other Cervical Procedures Performed is a category used to indicate if cervical diagnostic procedures other than those specified above were performed to determine a final diagnosis. Only diagnostic procedures performed as management of a suspected cervical lesion, such as endometrial biopsy, the excision of endocervical polyps or gynecologic consultation should be reported in this item. It is appropriate to report biopsies of other genital structures such as the vagina or vulva only for women who do not have a cervix. **This category should not be used for the reporting of a repeat Pap test or for treatment procedures such as cryosurgery, hysterectomy, laser, or cautery.** The MDEs are not a reflection of the client's medical chart, but rather a subset of that information. We request that Providers do not report routine procedures such as pregnancy tests, urinalysis, etc., as Other Diagnostic Procedures. Items reported in this category should be limited to actual procedures performed to determine a diagnosis of cancer or not cancer. Reclaiming inappropriate "other" responses that should be reported in categories listed above is time-consuming and could potentially result in the loss of valuable data.

There are many procedures that can be performed in conjunction with those procedures specified above to *support* the result of that procedure, but which are not a diagnostic procedure that *provides* a diagnosis. These types of procedures should not be reported as an Other Cervical Procedure. These procedures include; Cervicography, Pelvic ultrasound, or Cervical Computed Axial Tomography (CAT) scan. If these procedures are reported to your Program as the only diagnostic test provided to a participant, a case manager should review the case more thoroughly.

Final Cervical Cancer Diagnosis

The “**Status of Final Diagnosis**” or “**Diagnostic Disposition**” is the status of the final outcome of all the cervical screening and diagnostic tests provided during this screening cycle. The following choices are available to conclude the disposition of final diagnosis:

Work-up Complete: A status of 1 (Work-up Complete) indicates that the diagnostic testing is complete, and that the final diagnosis and date of final diagnosis are known. If a response of Work-up Complete is indicated, then at least one additional cervical diagnostic procedure must have been performed, and a Final Diagnosis and Date of Final Diagnosis must be completed.

Lost to Follow-up: A status of Lost to Follow-up should be reported if prior to the initiation or completion of diagnostic work-up a participant moves to a location beyond the Program's range of service delivery (e.g. to another country), or she cannot be located by the Program (e.g. moved). Lost to Follow-up should be reported when tracking efforts have been attempted in accordance with the Program's written protocol, but were unsuccessful. While such cases are simply reported to the CDC as "Lost", Providers should track more detailed information about each "lost" case to better manage their program's outcome. If a participant dies prior to the initiation or completion of diagnostic work-up, the status should also be indicated as Lost to Follow-up.

Work-up Refused: A status of Work-up Refused should be reported if a participant severs her relationship with the Program. For example, a participant may decline the recommended diagnostic work-up, or may choose to have the diagnostic work-up performed by a provider outside of the program.

***Irreconcilable: Note:** This choice is not available to Providers and should not be used in any circumstance. A status of "Irreconcilable" is available to administrative staff and 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 MDE data record. For example, a clinician might refer a participant for short-term follow-up instead of following the clinical guidelines for immediate diagnostic work-up. In such cases, DPH will enter "Irreconcilable" to indicate a cycle that has been reviewed and subsequently closed with an irreconcilable status. It is recommended by the CDC that Programs do not include irreconcilable status of final diagnosis on their data collection forms for providers to select. The intent of irreconcilable status of final diagnosis is for administrative use at the Program's central data location, and not at the provider level. Its intended use is to help Programs manage the records in the Audit 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. Final diagnosis is an important outcome measure for the CBCCEDP. Thus it is critical that these data are complete, timely, and accurate.

Final Diagnosis : This item should always be completed when Additional Procedures Needed to Complete Cervical Cycle are performed and the Status of Final Diagnosis is Work-up Complete. The classifications for a final cervical cancer screening diagnosis are as follows:

- **Normal/Benign reaction/Inflammation :** If the cervical findings are "normal", then the cervical final diagnosis should be reported as Normal/Benign reaction/Inflammation. If the cervical diagnosis is "Normal", but in addition a diagnosis of VAIN was reported, then the Final Diagnosis should also be reported as Normal.
- **HPV/Condylomata/Atypia**
- **CINI/Mild dysplasia (biopsy diagnosis)**
- **CINII/Moderate dysplasia (biopsy diagnosis)**
- **CINIII/Severe dysplasia/Carcinoma in situ (stage 0) or Adenocarcinoma In Situ** of the cervix (AIS) (biopsy diagnosis) : A final diagnoses of Adenocarcinoma In Situ (AIS) of the cervix should

be reported as CIN3/CIS/AIS. AIS *of the cervix* is an in situ pre-cancerous condition that requires treatment.

- **Invasive cervical carcinoma (biopsy diagnosis)** The term “invasive cervical carcinoma” is meant to refer to histologic characteristics of tumors found primarily within the cervix. Final diagnoses of Adenocarcinoma *of the cervix*, Invasive Adenocarcinoma *of the cervix*, or squamous cell carcinoma *of the cervix* should be reported as Invasive cervical carcinoma. These are invasive cervical carcinoma diagnoses that require treatment.
- **Low grade SIL (biopsy diagnosis)** Low grade SIL is not recommended biopsy diagnoses; however, some pathologists use this terminology when reporting cervical biopsy results. This diagnosis is an alternative to the diagnoses above and should only be reported if the diagnoses above are not offered.
- **High grade SIL (biopsy diagnosis)** High grade SIL are not recommended biopsy diagnoses; however, some pathologists use this terminology when reporting cervical biopsy results. This diagnosis is an alternative to the diagnoses above and should only be reported if the diagnoses above are not offered.

Final Diagnosis Other Cancers of the vagina, vulva, ovary, uterus or endometrium detected during cervical screening should only be reported as a final diagnosis of 7 (Other) when the participant does not have a cervix. If the participant has a cervix, then the Final Diagnosis should reflect her cervical findings. If the cervical diagnosis is “Normal”, but in addition a diagnosis of VAIN was reported, then the Final Diagnosis should be reported as 1 (Normal). You may collect the non-cervical finding, but it should not be reported in the MDEs. Sarcomas that are of a histologic type of primary cancer that occurs in the cervix may be considered invasive cervical carcinoma but should be reported as Other in the program screening record. Melanoma, which is a skin based cancer that can occur anywhere, and lymphoma and leukemia, which are lymphatic and blood system cancers, do not typically reflect cervical findings and should not be reported as Other cervical final diagnoses.

The MDEs are a data set for the reporting of cancer incidence. Therefore, cancer recurrences should not be reported in the cancer screening record. In the event that a second diagnosis of cervical cancer is reported for a participant, the DPH should share the necessary information with its Cancer Registry to determine if the cancer is a new primary or a recurrence. If the cervical cancer is determined to be a new primary, then it may be reported in the cervical screening record. If the cervical cancer is determined to be a recurrence, the final diagnosis should be modified by the Program’s data management center to report Other with a free text description entered in the item provided for that purpose. Such cases should be documented in detail in the Program’s data system and also in the MDE Submission Narrative document that accompanies the MDE file. Final diagnosis is an important outcome measure for the NBCCEDP. Thus it is critical that these data are complete, timely, and accurate.

Cervical Cancer Treatment

Treatment Needed : It is up to the clinician to determine the course of action for a participant screened through this program and found to have cervical cancer or precancerous lesions (Invasive Cervical Cancer or Cervical intraepithelial neoplasia Grade 3 (CIN III)). This decision needs to be recorded in the participant's Program record. No Program funds can be used for cancer treatment however participants diagnosed through the CBCCEDP are eligible for treatment services through Medicaid as specified in the CT Breast and Cervical Cancer Treatment Act. For more information about enrollment into Medicaid for cancer treatment see the **Procedure for Becoming a Qualified Entity (QE) and the W-1BCC Fast Form** in the CCHDIHSP Policy Manual Section I Requirements and Guidance. In some instances, a diagnostic procedure may also constitute standard treatment. This is often true when a Loop Electrode Excisional Procedure (LEEP) is performed as a diagnostic procedure. In such cases, the procedure should be reported as a cervical diagnostic procedure and as a treatment procedure. The Status of Treatment should be Treatment Initiated, and the Date of Treatment Status should be the date of the procedure. In most of these instances, the Date of Final Diagnosis and the Date of Treatment Status will be the same.

A status of Treatment Not Needed should be reported only in instances where the clinician and the participant jointly agree that treatment of the cancer or precancerous lesion would adversely affect the participant's quality of life. This may occur, for example, in cases of late or end stage cancers. It is not appropriate to record that cervical cancer treatment is not needed for cases where cervical cancer or precancerous lesions are not diagnosed. The CDC expects to see documentation of a treatment status for the following final diagnoses: CIN 2, CIN 3, High grade SIL, and Invasive cervical cancer.

Recommended Treatment: For the purpose of the CBCCEDP, CDC requires the reporting of standard or conventional treatments only. Note however that treatment using experimental drugs, such as those used in clinical trials, may be reported as Treatment Started.

A status of Treatment Refused should be reported In the event that a participant chooses a form of non-standard or alternative treatment.

Disposition or Status of Recommended Treatment:

The fact that a participant is referred for standard treatment is not sufficient confirmation that treatment has been started. A participant should be classified as having started treatment only after the Program has confirmed that a plan for standard treatment of the cancer has been developed and started. The following are categories for classifying the disposition of treatment:

Treatment Started: The Status of Treatment is an important outcome measure for the CBCCEDP. It is important to know the percentage of women diagnosed with breast cancer that have started treatment. Thus it is critical that these data are complete, timely, and accurate. A participant should be classified as having started treatment only after the Program has confirmed that a plan for standard treatment of the cancer has been developed and started.

A status of Treatment Refused should be reported in the event that a participant chooses a form of non-standard or alternative treatment. For the purpose of the CBCCEDP, CDC requires the reporting of standard or conventional treatments only. Note however that treatment using experimental drugs, such as those used in clinical trials, may be reported as Treatment Started.

Lost to Follow-up: A status of Lost to Follow-up should be reported if following a diagnosis but prior to the initiation of treatment a participant moves to a location beyond the Program's range of treatment services (e.g. to another state or country), or she cannot be located (e.g. moved). Lost to Follow-up should be reported when tracking efforts have been attempted in accordance with the Program's written protocol, but were unsuccessful. While such cases are simply reported to the CDC as "Lost" Programs should track more detailed information about each case to aid in better management of Program outcome. If a participant dies prior to the initiation of treatment, the status should be reported as Lost to Follow-up.

Treatment Refused: A status of Treatment Refused should be reported if a participant severs her relationship with the Program following diagnosis but prior to the initiation of treatment; or in the event that a participant chooses a form of non-standard or alternative treatment. For the purpose of the NBCCEDP, CDC requires the reporting of standard or conventional treatments only. Note however that treatment using experimental drugs, such as those used in clinical trials, may be reported as 1 (Treatment Started) If a Participant is refusing treatment, it's important to document the reason why. This information can be entered into clinical notes and can also be entered into the final diagnosis screen of the Med-IT® system.

Treatment Not Needed: A status of Treatment Not Needed should be reported in instances where the clinician and the participant jointly agree that treatment of the cancer would adversely affect the participant's quality of life. This may occur, for example, in cases of late or end stage cancers. In some instances, a diagnostic procedure may also constitute standard treatment. In such cases, the procedure should be reported as a breast diagnostic procedure. The Status of Final Diagnosis/Imaging should be reported as Work-up Complete; and a Final Diagnosis and Date of Final Diagnosis should be reported. The Status of Treatment should be Treatment Started, and the Date of Treatment Status should be the date of the procedure. In most of these instances, the Date of Final Diagnosis and the Date of Treatment Status will be the same.

Date of Disposition or Status of Recommended Treatment

If the Status of Treatment is Treatment Started, Lost to Follow-up, Refused, or Treatment Not Needed, then this item should be completed; otherwise this item should be left blank.

If the Status of Treatment is Treatment Started, then report the date on which the participant began standard treatment. If the Status of Treatment is Lost to follow-up, Treatment Refused or Treatment Not Needed, then the "Date of Treatment Status" item must be completed with an administrative closeout date. Each Program is expected to have a "Lost to Follow-up Policy" which outlines the number and types of attempts that the Program should make to contact a participant before she is declared Lost to Follow-up. The date of treatment status that is reported for a "Lost to Follow-up" case should be the

date that the policy guidelines are satisfied. This is the administrative closeout date for the record. Also, if a participant dies before treatment is initiated, then enter the date of death as the administrative closeout date for this item. The CDC realizes that in many cases attempts to contact a participant continue well beyond this administrative date. In the event that these efforts are successful and the participant returns to the Program, a new screening cycle should be started. Similarly, each Program should have a policy that outlines the requirements for determining that a participant has refused treatment. The date of treatment status that is reported for a "refused" case should be the date that the policy guidelines are satisfied. To review the CBCCEDP policies on Lost to Follow-Up and Refused Treatment refer to the **Lost to follow-Up** Protocol in the Policy and Procedure Manual Section II - Direct Services.

APPENDIX A – Model Clinical Categories

Model Clinical Categories

The following table was designed to assist grantees in clinical categories to MDE categories and was taken from CDC's Data User Manual MDE Version 6.0; January 1, 2009; Page 2-21.

At the request of the Programs, and to propose a model for the collection of the CBE data at the clinical level, the following categories were proposed by a working group of the CDC and Program participants in the spring of 1994. The use of these clinical categories on data collection tools is strongly recommended.

- 1 = Normal exam
- 2 = Benign finding (such as fibrocystic changes, diffuse lumpiness or nodularity)
- 3 = Discrete palpable mass (includes masses that may be cystic or solid, as well as indistinct palpable masses)
- 4 = Bloody or serous nipple discharge
- 5 = Nipple or areolar scaliness
- 6 = Skin dimpling or retraction
- 7 = Previous normal CBE in past 12 months - CBE not done today
- 8 = CBE not done today - other or unknown reason
- 9 = CBE refused
- 10 = Discrete palpable mass – previously diagnosed as benign

Clinical categories - TRANSLATED TO -	MDE categories
1, 2, 10	1
3, 4, 5, 6	2
7	3
8, 9	4

The CDC understands that category 5 and 6 are not always an indication of breast cancer. However, when these are seen, it is necessary to rule out cancer, and therefore diagnostic evaluation is needed.

Note: the above clinical categories may be collapsed, or other categories added, as deemed appropriate, as long as the translation to MDE categories is not affected.

APPENDIX B – Alert Values Protocol

Alert Values Protocol

Alert values (very high values) for weight, blood pressure, glucose, and cholesterol pose a danger to a participant's health. Very high values, singly or in combination can cause damage to the blood vessels (arteriosclerosis), brain (stroke), heart (heart attack), kidneys (renal failure), and eyes (compromised vision/blindness). For these reasons participants with heart disease screening alert values must be referred for medical evaluation and treatment within a seven day time, with the day of the office visit counting as day 1.

Policy:

- Participants with alert values are required to be referred and seen for medical evaluation and treatment immediately (the same day) or within seven days beginning the day of the office visit. This includes all providers and sub-contractors.
- The options for the participant to be seen by a health care professional include the clinic, office or emergency room. If a clinic or office visit cannot be arranged within the seven day time frame, the participant should be referred to the emergency room.
- Because of the serious implications alert values represent for the health status of program participants, there are no exceptions to this policy.
- Project directors are responsible for the Program's full compliance with the Alert Values Protocol.

Procedures:

- Providers and sub-contractors are required to notify the provider case manager of an alert value by telephone and fax the day the alert value is identified to allow sufficient time to arrange for medical follow-up within the seven day time frame.
- Providers and all sub-contractors need to ensure that the participant with an alert value will be seen by a health care professional in a clinic, office, or emergency room setting within the seven day time frame.
- Providers need to track participants by telephone to ensure that they keep their medical appointment.
- Providers are responsible for contacting the medical facility where the participant was evaluated for the alert value(s) to ensure that the participant kept the appointment and to identify treatment data.
- If provider staff are having difficulty in arranging for a participant to be medically evaluated within the seven day time frame, or if there are financial barriers, the project director should be notified immediately to assist in the resolution of the problem(s).
- Project directors need to ensure that all provider staff and sub-contractors are educated/re-educated concerning the management of alert values.
- If women with alert screening values are not seen in the expected time frame, project directors should consider doing an assessment of the referral procedures to identify areas for improvement.

Alert Screening Values

Values	Referral Level
Systolic Blood Pressure	> 180 mmHg
Diastolic Blood Pressure	> 110 mmHg
Fasting or Non-Fasting Total Blood Cholesterol	> 400 mg/dL
Fasting or Non-Fasting Blood Glucose	≥ 275 mg/dL
Fasting or Non-Fasting Blood Glucose	≤ 50 mg/dL

Provider Documentation:

- Providers need to document both the date the participant with alert values was seen for medical evaluation and the treatment information on the Screening and Assessment Form in Med-IT using the drop down menu.
- Providers should document notes in the notes section of the form indicating the reasons why a participant did not receive medical evaluation and treatment within the seven day time frame, barriers that prevented the participant from being seen within the time frame, and what the provider has done to ensure that the participant receives medical evaluation and treatment.

DPH Documentation:

- The Centers for Disease Control and Prevention (CDC) requires DPH to provide detailed documentation on each and every participant with an alert value who is not seen within the seven day time frame. The documentation must include alert value test results along with a detailed explanation as to why the participant was not seen within the time frame, barriers that prevented the participant from being seen within the time frame, and what the provider has done to ensure that the participant receives medical evaluation and treatment.

APPENDIX C – Mapping ICD-O Codes for CRC Histology

Mapping ICD-O codes for CRC Histology

The following tables was designed to assist grantees in mapping specific IDC-O morphology codes to the CCDE Histology categories and was taken from CDC’s Data User’s Manual CCDE Version 1.0; March 31, 2010; Pages 103-104

CCDE Colorectal Histology Categories	International Classification of Disease for Oncology, 3 rd 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)	<p>8140-8147, 8160-8162, 8180-8210, 8212, 8214-8221, 8250-8260, 8262, 8264-8506, 8520-8550, 8560, 8570-8573, 8940-8941 (<i>with behavior codes of /0</i>)</p> <p>8140/0 Adenoma, NOS 8210/0 Adenomatous polyp, NOS 8212/0 Flat adenoma 8220/0 Adenomatous polyposis coli 8221/0 Multiple adenomatous polyps</p>
5=Adenoma, tubular (no high-grade dysplasia noted)	<p>8211 (<i>with behavior code of /0</i>)</p> <p>8211/0 Tubular adenoma, NOS</p>
6=Adenoma, mixed tubular villous (no high-grade dysplasia noted)	<p>8263 (<i>with behavior code of /0</i>)</p> <p>8263/0 Tubulovillous adenoma, NOS</p>
7=Adenoma, villous (no high-grade dysplasia noted)	<p>8261 (<i>with behavior code of /0</i>)</p> <p>8261/0 Villous adenoma, NOS</p>
8=Adenoma, serrated (no high-grade dysplasia noted)	<p>8213 (<i>with behavior code of /0</i>)</p> <p>8213/0 Serrated adenoma</p>
9=Adenoma with high-grade dysplasia (includes in situ carcinoma)	<p>8140-8147, 8160-8162, 8180-8221, 8250-8506, 8520-8550, 8560, 8570-8573, 8940-8941 (<i>with behavior codes of /2</i>)</p> <p>8140/2 Adenocarcinoma in situ, NOS Adenocarcinoma in situ in adenomatous polyp 8210/2 Adenocarcinoma in situ in villous adenoma 8261/2 Adenocarcinoma in situ in tubulovillous adenoma 8263/2</p>

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CCDE Colorectal Histology Categories	International Classification of Disease for Oncology, 3 rd Edition, Acceptable Morphology Codes and Terminology from Common Codes
10=Adenocarcinoma, invasive	8140-8147, 8160-8162, 8180-8221, 8250-8506, 8510, 8520-8550, 8560, 8570-8573, 8940-8941 <i>(with behavior codes of /3)</i>
	8140/3 Adenocarcinoma, NOS 8141/3 Scirrhou adenocarcinoma 8210/3 Adenocarcinoma in adenomatous polyp
	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 <i>(with behavior codes of /3)</i> 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

APPENDIX D – Alert Values Protocol

Connecticut Department of Public Health Heart Disease Screening Services



Alert Values Protocol

Alert values (very high values) for weight, blood pressure, glucose, and cholesterol pose a danger to a participant's health. Very high values, singly or in combination can cause damage to the blood vessels (arteriosclerosis), brain (stroke), heart (heart attack), kidneys (renal failure), and eyes (compromised vision/blindness). For these reasons participants with heart disease screening alert values must be referred for medical evaluation and treatment within a seven day time, with the day of the office visit counting as day 1.

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- The options for the participant to be seen by a health care professional include the clinic, office or emergency room. If a clinic or office visit cannot be arranged within the seven day time frame, the participant should be referred to the emergency room.
- Because of the serious implications alert values represent for the health status of program participants, there are no exceptions to this policy.
- Project directors are responsible for the Program's full compliance with the Alert Values Protocol.

Procedures:

- Providers and sub-contractors are required to notify the provider case manager of an alert value by telephone and fax the day the alert value is identified to allow sufficient time to arrange for medical follow-up within the seven day time frame.
- Providers and all sub-contractors need to ensure that the participant with an alert value will be seen by a health care professional in a clinic, office, or emergency room setting within the seven day time frame.

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- Providers need to track participants by telephone to ensure that they keep their medical appointment.
- Providers are responsible for contacting the medical facility where the participant was evaluated for the alert value(s) to ensure that the participant kept the appointment and to identify treatment data.
- If provider staff are having difficulty in arranging for a participant to be medically evaluated within the seven day time frame, or if there are financial barriers, the project director should be notified immediately to assist in the resolution of the problem(s).
- Project directors need to ensure that all provider staff and sub-contractors are educated/re-educated concerning the management of alert values.
- If women with alert screening values are not seen in the expected time frame, project directors should consider doing an assessment of the referral procedures to identify areas for improvement.

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Fasting or Non-Fasting Blood Glucose	≤ 50 mg/dL

Provider Documentation:

- Providers need to document both the date the participant with alert values was seen for medical evaluation and the treatment information on the Screening and Assessment Form in Med-IT using the drop down menu.
- Providers should document notes in the notes section of the form indicating the reasons why a participant did not receive medical evaluation and treatment within the seven day time frame, barriers that prevented the participant from being seen within the time frame, and what the provider has done to ensure that the participant receives medical evaluation and treatment.

DPH Documentation:

- The Centers for Disease Control and Prevention (CDC) requires DPH to provide detailed documentation on each and every participant with an alert value who is not seen within the seven day time frame. The documentation must include alert value test results along with a detailed explanation as to why the participant was not seen within the time frame, barriers that prevented the participant from being seen within the time frame, and what the provider has done to ensure that the participant receives medical evaluation and treatment.

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