Cancer Prevention and Early Detection Program Manual

Patient/Health Navigation and Clinical Services Strategies

What types of organizations are eligible for this strategy?

- Health systems
- Network organizations are not eligible for these strategies.
- Community-based organizations are not eligible for these strategies

Only organizations that apply and are funded for the Patient/Health Navigation with Clinical Services Strategies will implement these activities. Organizations funded for these strategies will be referred to only as "organizations" throughout this section.

Overview

The Patient/Health Navigation (PN/HN) and Clinical Services (CS) strategies are known publicly as the Women's Wellness Connection or WWC.

The Patient/Health Navigation strategy is an interpersonal approach that funds navigation of eligible, low-income women into timely and complete breast and cervical cancer screening services. This strategy is aimed at reducing disparities by helping clients overcome barriers. Patient/Health Navigation is defined as "individualized assistance offered to clients to help overcome health care system barriers and facilitate timely access to quality screening and diagnostics as well as initiation of treatment services for persons diagnosed with cancer." Organizations must have CDPHE approval for the group(s) of women (insured vs. uninsured/underinsured) to which Patient/Health Navigation services will be provided through their Cancer Prevention and Early Detection contracts.

The Clinical Services Strategy is an individual-level approach that funds breast and cervical cancer screening and diagnostic procedures. This strategy is aimed at reducing disparities by reducing out-of-pocket costs of screening for eligible low-income, uninsured or underinsured women. The Clinical Services Strategy for eligible uninsured or underinsured women cannot be implemented without also implementing the Patient/Health Navigation Strategy for this same group of women. These combined strategies will sometimes be referred to as the Patient/Health Navigation with Clinical Services strategy.

Client Eligibility and Enrollment in Patient/Health Navigation and Clinical Services (WWC)

Organizations funded for Patient/Health Navigation and Clinical Services must determine if their clients are eligible for Patient/Health Navigation or Clinical Services. During eligibility assessment, all uninsured clients should be referred to Health First Colorado or Connect for Health Colorado for assessment of eligibility for Health First Colorado or subsidized marketplace health insurance coverage.

Client enrollment and participation in Patient/Health Navigation or Clinical Services is voluntary.

Eligibility / Enrollment Requirement	Verification Frequency	Guidance	Patient/Health Navigation, Patient/Health Navigation with Clinical Services or Both
Woman	Verify at initial enrollment.	Self-report.	Both.
Breast services: at least 40 but less than 65 years of age.	Verify at initial enrollment.	A woman is no longer eligible once she turns 65. Women under age 40 are not eligible for breast services.	Both.
Cervical services: at least 21 but less than 65 years of age.	Verify at initial enrollment.	A woman is no longer eligible once she turns 65.	Both.
Have a family income at or below 250 percent of the Federal Poverty Level.	Verify annually and be sure to use the most current guidelines.	Self-report.	Both.
Lawfully present in the United States.	Verify at initial enrollment, must be signed prior to services being provided.	• Obtain a signed affidavit and verify required identification for each client before services are rendered. It is recommended that the lawful presence affidavit template be copied onto your organization's letterhead. • Keep the signed affidavit and proof used to verify lawful presence in the client's medical record. • Refer to the Cancer Prevention and Early Detection Program's website for more guidance on lawful presence requirements. • A lawful presence affidavit signed after Aug. 1, 2006, qualifies as up to date.	Both.

Eligibility / Enrollment Requirement	Verification Frequency	Guidance	Patient/Health Navigation, Patient/Health Navigation with Clinical Services or Both
		• Have client re-sign if lawful presence status changes (i.e. if client becomes a citizen). • Effective Jan. 1, 2017, lawful presence affidavits must reflect the program(s) for which the affidavit is being used. CDPHE has added "Cancer Prevention and Early Detection and WISEWOMAN" to the affidavit templates found on the website. • The affidavit template may be modified to include any additional programs at your organization that require an affidavit (inclusion of the programs on the shared form should be confirmed with the other program(s)). • If the organization is using an affidavit from a different program (example: Colorado Indigent Care Program), the organization must modify the template to add the Cancer Prevention and Early Detection Program or WWC, or have the client sign a Cancer Prevention and Early Detection Program specific affidavit when enrolling.	
Have insurance (see below for additional guidance).	Assess insurance status before patient/health navigation services are provided.	• If eligible for insurance, assist client to enroll before breast and cervical cancer screening procedures are provided. If a client is eligible for insurance and the organization is able to enroll her in insurance on the day of enrollment, she is considered "insured." • Document appropriate funding source for each procedure in eCaST (i.e. Medicaid, insurance).	Patient/Health Navigation for eligible insured women.
Have no health insurance or are underinsured (see below for additional guidance).	Assess insurance status before each CDPHE-funded breast and cervical cancer screening procedure is	Self-report.	Patient/Health Navigation with Clinical Services for eligible uninsured/underinsured women.

Eligibility / Enrollment Requirement	Verification Frequency	Guidance	Patient/Health Navigation, Patient/Health Navigation with Clinical Services or Both
	provided. This includes re-assessing insurance status at the time of follow-up or for diagnostic services occurring within the same screening cycle.		
Signed Combined Program Consent Form.	Client must sign at initial enrollment.	When a client signs this form, she is affirming that she: 1) understands program eligibility rules and coverage, 2) has answered all eligibility questions honestly, and 3) has knowingly agreed to participate in the program. • The consent must be signed prior to entering any data in eCaST. • Keep the signed consent form in the client's medical record.	Both.

CDPHE's aim is to help organizations provide WWC Patient/Health Navigation and Clinical Services to eligible clients in need. Therefore, if an agency has difficulty meeting the timelines outlined above for certain eligible clients or groups of eligible clients, the organization should discuss this difficulty with its CDPHE program coordinator to determine if any alternative options can be implemented to obtain the required paperwork from these clients. CDPHE cannot provide alternative options for clients who do not meet the age, income and lawful presence requirements of the program. Program forms are found on the Cancer Prevention and Early Detection Program website.

Additional Guidance on Insurance Status

- Clients who have Medicare Part A only and/or Colorado Indigent Care Program (CICP) are considered uninsured/underinsured and eligible for Patient/Health Navigation with Clinical Services.
- Clients who have Medicaid or Medicare Part B as health insurance are not eligible for Clinical Services.
- Some health plans may have copayments or other fees charged to the policyholder when preventive screening services are rendered. Organizations should obtain this information before providing services to determine insurance status of clients.
- Eligible tribal members and those who have Indian Health Services (IHS) coverage are eligible for Patient/Health Navigation with Clinical Services because the federal government considers

IHS the payer of last resort. Tribal members with other insurance coverage (Medicaid or private insurance) are not eligible for Patient/Health Navigation with Clinical Services.

Resources that may assist you in navigating clients through obtaining health care coverage include:

- Colorado Department of Health Care Policy and Financing.
- Colorado PEAK.
- Colorado Connect for Health.

Enrolling a Client Referred-in for Diagnostics

As long as all other eligibility criteria are met, a client may be enrolled in Patient/Health Navigation or Clinical Services to complete her diagnostic services until she has had a definitive cancer diagnosis. Examples include:

- A client referred to your organization from another provider who provided screening services.
- A client referred to Patient/Health Navigation or Clinical Services after using other funding for screening services (at your organization).
- A client with insurance coverage for screenings who is unable to afford the deductible for diagnostic tests (Note that insured clients who are referred for diagnostics may not be eligible for the Breast and Cervical Cancer Treatment Program [BCCP] through Health First Colorado).

Patient/Health Navigation Services

Clients often face significant barriers to accessing and completing cancer screening and diagnostics. Patient/health navigation is individualized assistance offered to clients to help overcome health care system barriers and facilitate timely access to quality screening and diagnostics as well as initiation of treatment services for persons diagnosed with cancer.

A patient/health navigator assists individuals in reducing and eliminating barriers to health care access and negotiating complex health delivery systems. In Colorado, training programs are available to prepare patient/health navigators for this role, ranging from community college certificate programs to online trainings to university offerings. Typically, patient/health navigators are employed by health systems, including primary care, specialty care and managed care facilities.

Examples of PN/HN activities may include:

- Assessing credible community resources, developing partnerships and making referrals for the patient population served.
- Care coordination.
- Connecting patients with resources.
- Working with patients that use the health system frequently to ensure appropriate access to care.

- Supporting and motivating health behavior change.
- Implementing population health strategies.

Required PN/HN activities may be provided by non-clinical professionals. Although PN/HN services vary based on an individual client's needs, at a minimum, patient/health navigation **must** include the following activities:

- Written assessment of individual client barriers to cancer screening, diagnostic services and cancer treatment. Examples include, but are not limited to, obtaining health care coverage, transportation, language and health literacy.
- Client education and support.
- Resolution of client barriers.
- Client tracking and follow-up to monitor progress in screening, diagnostic testing and cancer treatment
- Given the centrality of the client-navigator relationship, patient/health navigation must include a minimum of two, but preferably more, contacts with the client.
- Collection of data to evaluate the primary outcomes of patient/health navigation: client adherence to cancer screening, diagnostic testing and treatment initiation. Clients who are lost to follow-up also should be tracked.
- Documentation of all required PN/HN activities in the client's medical record.

Patient/health navigation is an individualized intervention and intensive in nature; priority should be given to navigate clients who otherwise would **not** complete the screening process.

PN/HN for Clients with Abnormal Screening Results

Clients who have abnormal screening results must receive follow-up services to the point of a final diagnosis. This is achieved through patient/health navigation to ensure clients enrolled in the program receive timely and appropriate diagnostic and treatment services. An abnormal screening result is determined based on nationally recognized screening guidelines identified in the Breast and Cervical Cancer Screening Procedures section below.

Required additional patient/health navigation activities may be provided by non-clinical professionals, but a qualified health care professional (Registered Nurse, Physician Assistant or Physician in good standing to provide health care in Colorado) must have oversight. These additional activities include:

- Notify the client of an abnormal result within two (2) weeks of the date the procedure was performed.
- Arrange diagnostic appointments on the client's behalf. Clients must not be given a referral list and asked to schedule their own appointments.

Terminating Patient/Health Navigation

Depending on screening and diagnostic outcomes, PN/HN services are terminated when a client (1) completes screening and has a normal result; (2) completes diagnostic testing and has normal results; (3) initiates or refuses cancer treatment. When a client concludes her cancer treatment and has been released by her treating physician to return to a schedule of routine screening and continues to meet Patient/Health Navigation or Clinical Services eligibility requirements, she may return to the program and receive all its services, including patient/health navigation.

Lost to Follow-Up/Refused Service Policy

Funding received from the U.S. Centers for Disease Control and Prevention (CDC) is contingent upon CDPHE meeting or exceeding several quality assurance parameters, including CDC Core Performance Indicators and State Performance Indicators. For more information on performance indicators, see the Quality Assurance and Improvement section below.

Lost to Follow-Up

- A client may be considered lost to follow-up when at least three contact attempts have been made and documented in the client's medical record.
- This documentation should include the type of contact attempted, the date and the outcome.
- If the client has a valid address, at least one of the contact attempts should be a certified letter with a return receipt.
- A copy of the certified letter and the return receipt should be kept in the client's medical record.

Refused Service

- Every client has the right to elect or refuse diagnostic services or treatment.
- A client is considered to have refused service when one of the following has been carefully documented in the client's medical record:
    - She has verbally refused the follow-up care recommended.
    - She has refused in writing the follow-up care recommended.
- Documentation of the informed refusal should be kept in the client's medical record. Documentation should include what is being refused and that the client has been informed of the risks involved if recommended follow-up is not completed.

Tracking and Documentation

A client contact and tracking system must be in place to notify clients of abnormal results. Contacts with a client should be clearly documented in a client's medical record and should include what type of follow-up is needed, the recommended timeframe for follow-up and the clinical implications if the follow-up does not occur.

Breast and Cervical Cancer Screening Procedures

Organizations providing Patient/Health Navigation to insured clients are required to comply with the clinical guidelines stated below, **except:**

- **CDPHE-funded clinical procedures are not reimbursable for insured clients.** All references in the section below to reimbursement of clinical procedures are not applicable.
- **Pre-approval for procedures is not required.** Approval from the nurse consultant for breast MRIs, second cervical or breast biopsies, and active treatment following a diagnosis determined by excisional biopsy is not required.

Breast and cervical cancer screening procedures provided under the Patient/Health Navigation and/or Clinical Services strategies may be carried out by the funded organization or through subcontracts (for uninsured/underinsured clients) or referral networks (for insured clients) with other health systems. However, the funded organization must perform basic breast and cervical cancer screening services on site. Basic screening services include breast and cervical health history assessment, breast and cervical health education, clinical breast exams, and pelvic exams with Pap and HPV tests. These services are covered in more detail below. The funded organization must be the organization ultimately responsible for the care and follow-up of the clients it enrolls in these programs. In other words, each organization must "own" and "manage" the clients it enrolls in Patient/Health Navigation and/or Clinical Services.

Patient/Health Navigation and Clinical Services clinical policies are not intended to limit client care or interfere with the clinical decision-making of individual providers. However, organizations must adhere to clinical guidelines to ensure appropriate use of program funding and procedure reimbursement (Clinical Services only) for enrolled clients. Provider discretion may be used to provide procedures beyond the clinical policies, but CDPHE is not able to reimburse for these procedures.

Breast Cancer Screening Guidelines

Patient/Health Navigation and Clinical Services breast cancer screening guidelines are based on nationally recognized clinical guidelines from organizations such as the U.S. Preventive Services Task Force (USPSTF), American College of Obstetricians and Gynecologists (ACOG), National Cancer Institute (NCI), American Cancer Society (ACS), and with advice from the program's Medical Director. National guidelines and recommendations do not replace clinical judgment based on individual circumstances.

1. Breast Health History

   A breast health history must be recorded in the client's chart. Breast health history should include, at a minimum, questions about:

   - Personal history of breast cancer.
   - First degree relative with breast cancer (e.g. mother/father, sister/brother, daughter/son).
   - New breast symptoms during the past three months.

Collecting a comprehensive family history to assess breast cancer risk is highly encouraged. This may include family history of prostate cancer, ovarian cancer, and BRCA1 or 2 gene mutations.

2. Breast Health Education

Breast health education must be provided and documented in the client's chart and eCaST to receive reimbursement for breast cancer screening services in the absence of a breast procedure such as a clinical breast exam (CBE) or mammogram. Education must be provided in the context of an office visit. Education may be provided by the provider or other trained staff to the client in verbal or written form. Breast health education should include, at a minimum, information about:

- Breast cancer screening intervals.
- The risks and benefits of mammography screening.
- Risk factors for developing breast cancer.
- Symptoms of breast cancer.
- How to reduce the risk of breast cancer:
    - Stay physically active.
    - Maintain a healthy weight.
    - Weight the risks of breast cancer with longer term combination (estrogen & progestin) hormone therapy against potential benefits for the individual client.
    - Know the risks and benefits of HRT.
    - Limit the amount of alcohol consumed.

a. NBCCEDP's *Breast Cancer Facts* client handout can be used to meet this education requirement. This handout can be found here.

3. Clinical Breast Exams (CBE)

A CBE may be provided yearly at the discretion of the provider. Yearly CBEs are considered optional and may be performed based on the provider's and the client's determination of need. Performance of a CBE is not required to receive reimbursement for breast cancer screening services. However, an office visit is required.

4. Annual Breast Health/Breast Education Visit

Organizations may be reimbursed for clients who have office visits and are determined by a mid-level, or higher, provider to not need a breast screening after review of their health history, and 2) have a visit that includes breast health history and education. Breast health history and education (as detailed in #1 and #2 above) must be completed and documented in the chart and eCaST to receive reimbursement in absence of a breast procedure (i.e. CBE/mammogram).

5. Screening Mammography

- The Patient/Health Navigation and Clinical Services Strategies follow the U.S. Preventive Services Task Force (USPSTF) recommendations for payment of Clinical Services procedures. Although USPSTF recommends (Grade B) biennial screening, annual screening

mammograms are covered for clients ages 50-64. Annual screening is defined as 10 months or longer from the initial or previous screening.

- The Patient/Health Navigation and Clinical Services strategies cover targeted screening mammograms for clients ages 40 through 49. To be compliant with USPSTF guidelines, providers must avoid offering routine screening in this age group and instead, discuss potential benefits and harms of mammography screening to assist clients in making an informed choice. Women in this age group who place a higher value on the potential benefits than the potential harms may choose to begin screening before age 50. (USPSTF Grade C recommendation).
    - Counseling prior to scheduling a screening mammogram for a clients ages 40 through 49 should consist of a detailed conversation and agreement between a clinical staff member and client that includes a discussion of benefits and harms of screenings, a client's preference and breast cancer risk profile. Clinical staff may use the Targeted Screening Client Handout found on the website to provide this counseling. This counseling is more detailed and specific than the typical breast health education (described in #1, above). However, the more detailed counseling described here will also meet the requirements of breast health education.
    - The counseling should include specific information regarding:
        1. Risks, including false-positive and false-negative rates, rates of additional diagnostics, the detection of tumors that may not progress to cancer, anxiety/discomfort and overdiagnosis (i.e., tumors detected on screening that never would have led to clinical symptoms).
        2. Benefits, including a decreased risk in breast cancer mortality and, if diagnosed with breast cancer, the potential for less aggressive treatment.
- Some women with no family history of breast cancer will elect to wait until age 50 to start screening mammography; others may not be comfortable doing so.
- Organizations are encouraged to use one or more of the following three tools to assist providers and clients in determining whether clients ages 40 through 49 are appropriate candidates for screening mammograms.
    1. The USPSTF recommendations on Shared Decision-making About Screening and Chemoprevention.
    2. The National Cancer Institute's Breast Cancer Risk Assessment Tool.
    3. The following quick reference table:

Reasons a 40-49 year old client may be recommended to have a screening mammogram	Reasons a 40-49 year old client may not be recommended to have a screening mammogram

• Personal history of breast cancer. • Family history of breast cancer. • Previous breast biopsy. • Known genetic mutation (e.g. BRCA). • Unknown family history. • Excessive alcohol use, defined as 2 or more drinks daily. • Ashkenazi Jewish descent. • Nulliparity (never had children). • First child born after the age of 30. • Breast density of 51% or higher noted on previous mammogram. • History of chest mantle radiation for Hodgkin Lymphoma or non-Hodgkin Lymphoma.	• Has no identifiable factors for increased risk. • Hesitant about the possible harms of screening mammography. • Feels the possible harms are greater than the benefits in her case.

    - Meeting the CDC's Screening Core Performance Indicator for mammograms (at least 75 percent of all mammograms performed should be provided to clients who are 50 years of age and older) continues to be a priority of the Patient/Health Navigation and Clinical Services strategies. Recruitment efforts should continue to focus on this priority population.
- Breast Ultrasound or Automated Whole Breast Ultrasound is not covered when used as a screening method.
- 3D tomography (tomosynthesis) is not a covered screening or diagnostic procedure (USPSTF Grade I recommendation).

Breast Diagnostics and Management of Abnormal Breast Findings

Breast diagnostic services are covered for all clients eligible for Clinical Services if they have breast symptoms, abnormal CBEs, abnormal screening mammograms or referrals for diagnostic work-ups.

Requirements for Management of Abnormal Breast Exams or Imaging Results:

The 2011 Breast Cancer Diagnostic Algorithms for Primary Care Providers (4th Ed.) must be used by Patient/Health Navigation and Clinical Services organizations to guide clinical decision-making in the workup of breast abnormalities. These algorithms also may be used to assess risk of breast cancer. Also included in the algorithms are clinical tools, including core competencies of a clinical breast exam, CBE results documentation form, and a breast cancer history and risk assessment client information form. Copies of the algorithms can be downloaded here.

All client contacts and attempted contacts regarding abnormal breast cancer screening and diagnostic tests must be documented in the client's chart.

- Breast Biopsy
    - Organizations will be reimbursed for a breast biopsy of a suspicious breast mass or lesion whenever it is indicated or recommended by a physician. Organizations will not be

reimbursed for surgical procedures on benign breast masses for cosmetic or pain management reasons.

- Organizations may receive additional reimbursement when additional breast biopsies are required to complete a diagnosis. Organizations will be reimbursed for second breast biopsy performed on the **same day**. Please email the nurse consultant once all biopsy results are entered in eCaST to ensure timely reimbursement.

- Clinical Concordance
  - Both a diagnostic mammogram and an ultrasound should be ordered to help complete a diagnostic evaluation for any clients with a suspicious CBE or suspicious breast symptoms. An abnormal CBE,even in the presence of a BI-RADS® 1 or BI-RADS® 2 finding on a screening or diagnostic mammogram, requires further investigation.
  - The CBE and diagnostic imaging results must be concordant before a diagnostic evaluation is considered complete. There may be cases in which a client with an abnormal CBE is sent for diagnostic imaging and only a mammogram is completed by the radiologist. Although the radiologist may consider his or her diagnostic workup complete, this does not mean that the workup is complete. Clinical concordance is typically achieved by:

    Repeating the CBE within 30 days to make sure the finding has either been resolved or is consistent with mammogram results.
    The ordering clinician comparing the imaging findings with abnormal CBE results to ensure the abnormality is explained by the imaging.
    Please email the nurse consultant once the provider has reviewed the case for clinical concordance and recommends no further follow-up of the abnormal CBE or recommends a repeat CBE to reassess the abnormal finding. Please review the "Abnormal CBE Clinical Concordance" policy found on WWC's website under the heading "Diagnostic algorithms."

- Ductograms and galactograms are covered when the procedure is being performed to rule out breast cancer.
- Magnetic Resonance Imaging (MRI)
  1. Breast MRI must have preapproval from the nurse consultant.
  2. Organizations will be reimbursed for screening breast MRI performed in conjunction with a mammogram when a client has:
     - A positive BRCA1 or BRCA2 gene mutation test.
     - A first-degree relative who is a BRCA carrier.
     - A lifetime risk of 20-25 percent or greater as defined by risk assessment models such as BRCAPRO that are largely dependent on family history.
  3. Breast MRI can also be reimbursed when used to better assess areas of concern on a mammogram or for evaluation of a client with a past history of breast cancer after completing treatment.
  4. Breast MRI should never be done alone as a breast cancer screening tool. Breast MRI cannot be reimbursed to assess the extent of disease in women who already have been diagnosed with breast cancer.
  5. Providers should discuss risk factors with all clients to determine if they are at high risk for breast cancer. To be most effective, it is critical that breast MRI is done at facilities with dedicated breast MRI equipment and the ability to perform MRI-guided breast biopsies.

References

California Department of Public Health, Cancer Detection Section, Breast Expert Workgroup (2011). *Breast Cancer Diagnostic Algorithms for Primary Care Providers* (4th ed.). Retrieved from: https://qap.sdsu.edu/screening/breastcancer/bda/index3.html

U.S. Preventive Services Task Force (2011). *Screening for Breast Cancer*. Retrieved from: https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/breast-cancer-screening1

Cervical Cancer Screening Guidelines

Patient/Health Navigation and Clinical Services cervical cancer screening guidelines are based on nationally recognized clinical guidelines from organizations such as the American College of Obstetricians and Gynecologists (ACOG), American Society for Colposcopy and Cervical Pathology (ASCCP), American Society for Clinical Pathology, U.S. Preventive Services Task Force (USPSTF), and with advice from the program's medical director. Cervical cancer screenings may be covered for women ages 21 to 64. National guidelines and recommendations do not replace clinical judgment based on individual circumstances.

1. Cervical Health History

   A cervical health history should be recorded in the client's chart and in eCaST, if applicable, and should include:
   - History of Cervical Intraepithelial Neoplasia (CIN) 2/3 or cervical cancer.
   - Human Immunodeficiency Virus (HIV) status.
   - History of diethylstilbestrol (DES) exposure in utero (DES exposure factsheet).
   - History of conditions resulting in a compromised immune system, such as organ transplantation, chemotherapy or chronic corticosteroid treatment.
   - Hysterectomy status and whether cervix was removed with uterus.

2. Cervical Health Education

   Cervical health education must be provided and documented in the client's chart and eCaST to receive reimbursement for cervical cancer screening services in absence of a pelvic exam and/or Pap/HPV test. Education may be provided by the provider or other trained staff to the client in verbal or written form. Cervical health education should include, at a minimum, information about:
   - Cervical cancer screening intervals.
   - Options for cervical cancer screening.
   - Risk factors for developing cervical cancer.
   - Symptoms of cervical cancer.
   - How to reduce risk of cervical cancer (Get the HPV vaccine, follow up with your doctor if your Pap test results are not normal, don't smoke, use condoms during sex, limit your number of sexual partners).
   - NBCCEDP's Cervical Cancer Facts client handout can be used to meet this education requirement. This handout can be found here.

3. Pelvic Exams

A pelvic exam may be provided yearly at the discretion of the provider. If a pelvic exam is not being performed as a component of collecting a Pap test, it is considered optional and may be performed based on the provider's and client's determination of need. Performance of a pelvic exam is not required to receive reimbursement for cervical cancer screening services.
The USPSTF definition of a pelvic exam is a check of a woman's pelvic organs, including her vagina, vulva, cervix, uterus, fallopian tubes and ovaries. If a pelvic exam is being performed, it should include examination of each of these organs.

4. Annual Cervical Health/Cervical Education Visit

   Established clients and return office visits: After the clinician reviews the client's current health history, the clinician may deem it unnecessary for the client to have a cervical screening at the current visit. To receive reimbursement in the absence of a cervical exam/procedure (e.g. Pelvic/Pap/HPV), the clinician/agency must document the client's cervical health history and cervical education (as detailed in #1 and #2 above) in client's eCaST and medical records.

5. Screening for Cervical Cancer

   Screening for clients ages 21 through 64 at average risk for cervical cancer will be covered at routine screening intervals every three years with a Pap test alone. For clients ages 30 through 64, the option of providing cervical screening every five years with Pap and HPV co-testing is highly recommended.

USPSTF and ACS/ASCCP/ASCP	
Age to begin screening.	Age 21, regardless of the age of initiation of sexual intercourse or the presence of other behavior-related risk factors.
When to discontinue screening.	Older than 65 years if the woman has had adequate negative prior screening (3 negative Paps or 2 negative co-tests in the last 10 years). Women with a history of CIN2 or more severe diagnosis should continue routine screening for at least 20 years after diagnosis.
Screening intervals, ages 21 through 29.	Pap testing alone every 3 years.
Screening Intervals, ages 30 through 65.	Pap testing alone every 3 years or Pap testing with high risk HPV testing every 5 years.
Screening intervals for women with total hysterectomy.	No Pap test screening if the woman has had adequate negative prior screening and the woman does not have a cervix and does not have a history of CIN2 or a more severe diagnosis in the past 20 years or cervical cancer ever.
Use of high risk HPV Testing in conjunction with Pap test screening and follow-up in specific circumstances. For further recommendations for the use of high risk HPV testing in the management of abnormal Pap or biopsy results, please refer to the American	• Should not be used for screening in women under age 30. • HPV co-testing can be used in women ages 30 or older every 5 years. • If co-testing HPV positive and Pap test negative, then repeat co-testing in 12 months or do immediate HPV DNA typing for HPV16/18. ○ If co-testing is repeated at 12 months:

Society for Colposcopy and Cervical Pathology (ASCCP) algorithms.	▪ If positive HPV or Pap ≥ASC, refer to colposcopy. ▪ If Pap and HPV negative, repeat co-testing in 3 years. ○ If HPV DNA typing: ▪ If HPV 16 and 18 negative, then repeat co-testing in 1 year. ▪ If HPV 16 or 18 positive, then refer for colposcopy. • If co-testing HPV is negative and the Pap test is ASC-US, repeat co-testing in 3 years. (Source: ASCCP Updated Consensus Guidelines for Managing Abnormal Cervical Cancer Screening Tests and Cancer Precursors © 2013)

- Please note that the follow-up of abnormal results for women ages 21 through 24 may be different than for women age 25 and older.
- Women who have received the HPV vaccine should be screened according to the same guidelines as women who have not been vaccinated.
- Pap with HPV cotesting is highly recommended for screening clients ages 30 through 65 who have never been screened for cervical cancer or who have not been screened for cervical cancer in the past 5 years.
- For average risk clients, organizations will not be reimbursed for Pap and/or HPV testing obtained earlier than the recommended routine intervals listed above. If a Pap and/or HPV obtained prior to the routine screening interval are abnormal, organizations will be reimbursed for subsequent diagnostic testing (colposcopy/LEEP).
- HPV testing alone is not an approved screening strategy and will not be reimbursed.

Exceptions to Routine Screening Guidelines

- Organizations will be reimbursed for cervical cancer screenings in women with any of the following risk factors that may require more frequent cervical cancer screenings than recommended in the routine screening guidelines (which were intended for average-risk women).
- Clients who are infected with HIV or who are otherwise immunocompromised.
- Clients who were exposed to DES in utero.
- Organizations will be reimbursed for annual screening for clients after treatment for CIN 2/3 for at least two years or as determined by the provider's plan of care. The ASCCP recommends Pap and HPV co-testing at 12, 24 and 60 months, then routine testing for 20 years.
- Organizations will be reimbursed for annual Pap testing for clients with a history of cervical cancer.

Organizations will be reimbursed for one year follow-up Pap and/or HPV testing when it is recommended by the ASCCP Updated Consensus Guidelines for Managing Abnormal Cervical Cancer Screening Tests and Cancer Precursors (2012).

Screening Clients Who Have Had a Hysterectomy

- Organizations will be reimbursed for Pap testing alone every three years for clients who have had a hysterectomy for treatment of CIN 2/3, or who have a history of CIN 2/3 within the 20 years prior to having a hysterectomy.
- Organizations will be reimbursed for annual Pap testing for clients who have had a hysterectomy for treatment of cervical cancer.
- Clients who have had a hysterectomy with complete removal of the cervix for benign reasons and who have no history of CIN 2 or worse are not eligible for Patient/Health Navigation and Clinical Services cervical cancer screening services.

Management and Follow-Up of Abnormal Cervical Cancer Screening

- The ASCCP Updated Consensus Guidelines for Managing Abnormal Cervical Cancer Screening Tests and Cancer Precursors (2012) must be followed for management and follow-up of abnormal cervical cancer screening results. ASCCP guidelines and algorithms are available here. The ASCCP App can be downloaded here.
- All client contacts and attempted contacts regarding the abnormal cervical cancer screening and diagnostic tests must be documented in the client's chart.
- Organizations will be reimbursed for diagnostic excisional procedures such as LEEP when they are among acceptable options according to current ASCCP guidelines, such as follow-up for HSIL Pap test results in women over age 24.
- Organizations will be reimbursed for endometrial biopsy (EMB) in addition to colposcopy for evaluation of Atypical Glandular Cells (AGC). Organizations will not be reimbursed for EMB for reasons other than follow-up of an AGC Pap test. Please email the nurse consultant when management of a client includes both a colposcopy and EMB to ensure reimbursement for both procedures. Pre-approval is not necessary.
- Organizations will be reimbursed for a colposcopy and/or polypectomy regardless of the Pap test result for cervical lesions, cervical polyps or other suspicious cervical findings as determined by the provider. A normal Pap test cannot be used as a diagnostic indicator for a suspicious cervical finding on visual exam.
- Organizations may receive additional reimbursement when more than one cervical diagnostic procedure is required to complete a diagnosis. The amount reimbursed will be in addition to the first bundled payment system diagnostic reimbursement. Please email the nurse consultant once the biopsy results are entered in eCaST to receive timely reimbursement.

References

American College of Obstetrics & Gynecology. (2012). ACOG practice bulletin no. 131: Screening for Cervical Cancer. *Obstetrics and Gynecology, 120 (5),* 1222-1238.

Massad, L. S., Einstein, M. H., Huh, W. K., Katki, H. A., Kinney, W. K., Schiffman, M., Solomon, D., Wentzensen, N., Lawson, H. W. 2012 Updated Consensus Guidelines for the Management of Abnormal Cervical Cancer Screening Tests and Cancer Precursors. *Journal of Lower Genital Tract Disease, 17 (5)*, S1-S27.

U.S. Preventive Services Task Force (2012). *Screening for Cervical Cancer*. Retrieved from http://www.uspreventiveservicestaskforce.org/uspstf/uspscerv.htm.

Transgender Coverage

Transgender women (male-to-female), who have taken or are taking hormones and meet all program eligibility requirements, are eligible to receive Patient/Health Navigation and Clinical Services. Although there are limited data regarding the risk for breast cancer among transgender women, evidence has shown that long-term hormone use increases the risk for breast cancer among women whose biological sex was female at birth. While CDC does not make any recommendation about routine screening among this population, transgender women are eligible under federal law to receive appropriate cancer screening. CDC recommends that providers counsel all eligible women, including transgender women, about the benefits and harms of screening and discuss individual risk factors to determine if screening is medically indicated.

The Center of Excellence for Transgender Health and the World Professional Association for Transgender Health have developed consensus guidelines for the primary and gender-affirming care of transgender and gender non-binary people. Those guidelines include guidelines for "transgender women with past or current hormone use, breast-screening mammography in clients over age 50 with additional risk factors (e.g., estrogen and progestin use > 5 years, positive family history, BMI > 35)." These specific preventive care recommendations can be found for:

- Breast cancer screening in transgender men.
- Screening for breast cancer in transgender women.

Cancer Prevention and Early Detection funds may be used to cover Patient/Health Navigation and Clinical Services for eligible transgender men (female-to-male) who have not yet undergone a complete hysterectomy or bilateral mastectomy or who meet the "screening clients who have had a hysterectomy" guidance above.

National Transgender Resources

- The Substance Abuse and Mental Health Services Administration's Top Health Issues for LGBT Populations, Information & Resource Kit, 2012.
- National LGBT Health Education Center.
- CDC - LGBT Health.
- Health Resource and Services Administration - LGBT Health.

Colorado Transgender Resources

- The Center – Advancing LGBT Colorado, Health
- One Colorado
- The Center - Transgender Programs

Tobacco Use Assessment and Referral Policy

The CDC requires all National Breast and Cervical Cancer Early Detection Program (NBCCEDP) grantees assess all enrolled clients for tobacco use status and promote tobacco cessation services. CDPHE is committed to improving the health of its clients through improving screening, diagnosis, treatment and referral for tobacco cessation. The goal is to ensure that every client is screened for tobacco use, their tobacco use status is documented and clients who use tobacco are advised to quit.

Assessment of Tobacco Use Status

All clients enrolled in Patient/Health Navigation and Clinical Services should be evaluated for tobacco use at each visit. The USPSTF found reliable evidence that brief smoking cessation interventions, including screening, brief behavioral counseling (less than 3 minutes) and pharmacotherapy delivered in primary care settings are effective in increasing the proportion of smokers who successfully quit smoking and remain abstinent after one year.

Providers are encouraged to screen* for tobacco use status using the "5 As" intervention:

ASK	Identify and document tobacco use status for every client at every visit.
ADVISE	In a clear, strong and personalized manner, urge every tobacco user to quit.
ASSESS	Is the tobacco user willing to make a quit attempt at this time?
ASSIST	For the client willing to make a quit attempt, refer to the Colorado QuitLine directly at 1-800-QUIT-NOW (1-800-784-8669) or use the Fax-To-Quit form.
ARRANGE	Schedule follow-up contact, in person or by telephone, preferable within the first week after the quit date.

*Dependent upon client need, provider capacity, and clinic preference, the **ASK, ADVISE, REFER (AAR)** intervention model may also be used to assess for tobacco use.

ASK	Identify and document tobacco use status for every client at every visit.
ADVISE	In a clear, strong and personalized manner, urge every tobacco user to quit.
REFER	Connect clients who are ready to quit tobacco within the next 30 days to the Colorado QuitLine directly at 1-800-QUIT-NOW (1-800-784-8669) or use the Fax-To-Quit form.

QuitLine Referral Process

CDPHE strongly recommends that clients are referred to the Colorado QuitLine for free telephonic counseling and support during each quit attempt. Clients will receive help from trained quit coaches and access to stop-smoking medication, which have been shown to increase the success of their quit attempt.

To refer a client to the Colorado QuitLine, print out the Fax-To-Quit-Referral Form found here and fax it to 1-800-261-6259. Once this form has been completed and faxed to the QuitLine, a QuitLine staff member will contact the client. Clients can also visit the online program at Colorado QuitLine or call 1-800-QUIT-NOW (1-800-784-8669).

The Asian QuitLine provides services in Chinese, Korean and Vietnamese.

Organizations may also refer clients to other evidence-based cessations programs or resources.

For the Client Unready to Quit

For clients not ready to make a quit attempt, clinicians should use a brief intervention designed to promote the motivation to quit. Such clients may respond to brief motivational counseling interventions that are based on principles of Motivational Interviewing (MI), a directive, client-centered counseling intervention. The content areas that should be addressed in a motivational counseling intervention can be captured by the "5 Rs": relevance, risks, rewards, roadblocks and repetition. More information on these clinical interventions may be found in Treating Tobacco Use and Dependence: 2008 Update – Clinical Practice Guideline.

Marijuana Resources

- CDPHE marijuana resources.

Treatment Referral Services

Organizations must coordinate access to treatment services for clients diagnosed with cancer or an eligible precancerous condition. Organizations must establish relationships and/or subcontracts for referral sources for treatment services prior to offering screening services to any Patient/Health Navigation or Clinical Services client. Due to Health First Colorado's Creditable Coverage requirements, insured clients generally cannot be enrolled in Health First Colorado's Breast and Cervical Cancer Treatment Program (BCCP).

Uninsured clients enrolled in Patient/Health Navigation with Clinical Services may be eligible for Health First Colorado BCCP for treatment if they are diagnosed with breast or cervical cancer or eligible precancerous conditions through the program.

To be eligible for Health First Colorado BCCP, a client **must**:

- Have been diagnosed with breast or cervical cancer or an eligible pre-cancerous condition, and be in need of treatment. A list of eligible diagnoses can be found on the Cancer Prevention and Early Detection Program website.
- Be lawfully present in the United States for five years.
- Be younger than age 65.

- Not have creditable coverage.

Coverage is considered to be creditable if it provides any benefit for the treatment of breast or cervical cancer or precancerous conditions. A client does not have creditable coverage if the plan in which she is enrolled is limited in scope (e.g., excludes the coverage of breast and/or cervical cancer) or if she has exhausted the lifetime limits of her plan's benefits. If creditable coverage is lost at any time, the client may immediately apply for Health First Colorado BCCP.

Enrolling Clients into the Health First Colorado BCCP

Clients who meet the criteria above may be eligible for treatment through the Health First Colorado BCCP program. The enrollment process should begin within five business days after a breast or cervical cancer diagnosis occurs to complete the enrollment process within the program-required 10 business days.

Please have clients with incomes close to or below 138 percent of the Federal Poverty Level complete the online PEAK application to determine if they are eligible for regular Health First Colorado prior to beginning the enrollment process for BCCP. The client should receive a "real time" approval or declination notice after completing the application. If a client is approved for Health First Colorado through PEAK, there is no need to move forward with a BCCP application. If the client does not qualify for Health First Colorado through PEAK, follow the BCCP Enrollment Step List.

Presumptive Eligibility and Health First Colorado BCCP

Clients applying for Health First Colorado BCCP are eligible for presumptive eligibility (PE). PE allows a client to begin immediate treatment for breast or cervical cancer or an eligible precancerous condition the day the diagnosis is made. Once a PE number is given to the client by the PE hotline, treatment services will be covered by Health First Colorado. Once the client is enrolled in PE, she will receive full coverage during the presumptive eligibility period. The presumptive eligibility period is no more than 45 - 60 calendar days and ends on either: 1) the date on which a formal determination is made on the client's Health First Colorado Application for Health Coverage and Help Paying Costs, or 2) the last day of the month following the month in which the client was determined to be presumptively eligible. The PE period may not be extended.

Clients eligible for Health First Colorado BCCP are eligible for all benefits included in the State Medical Assistance Plan. The Colorado Department of Health Care Policy and Financing (HCPF) Health First Colorado BCCP coordinator and/or county Department of Social/Human Services will:

- Provide information to the client about services and benefits available through Health First Colorado.
- Assist the client in accessing health care services (such as transportation services or mental health services) or contacting the appropriate organization (such as an enrollment broker).
- Assist the client in applying for and accessing other assistance benefits for which she may qualify, e.g., home care allowance, food stamps, financial assistance, etc.

A client enrolled in Health First Colorado BCCP is eligible to receive full coverage until she is no longer in need of treatment, or it is determined that she no longer meets the eligibility criteria for the program. If the client remains in treatment beyond one year, renewed eligibility may be determined consistent with Health First Colorado's standard coverage redetermination requirements.

A client may be determined to be *no longer eligible* for Health First Colorado BCCP if:

- She does not complete the Health First Colorado application as described.
- She is no longer in need of treatment for breast or cervical cancer.
- She reaches age 65.
- She obtains other creditable coverage.

Clients who are determined no longer eligible will be notified by Health First Colorado in writing.

For more information on Health First Colorado BCCP please visit the HCPF website.

Enrolling Clients into Non-WWC Health First Colorado BCCP

Individuals who have been screened and diagnosed with breast or cervical cancer at a non-Clinical Services clinic also may be eligible for treatment through Health First Colorado BCCP. Other eligibility criteria remain the same. The following forms must be faxed to HCPF at 303-866-2573 to begin the enrollment process:

- The signature page of the full PEAK application (after application has been completed).
- The completed Presumptive Eligibility form.
- The non-WWC Provider Attestation.
- The completed verification of lawful presence.

For any questions regarding this process, please call Diane Stayton, Health First Colorado's BCCP Coordinator, at 303-866-2385.

Quality Assurance and Improvement

The program has established standards, systems, policies and procedures to monitor and assess current strategy effectiveness and to improve strategy performance.

Performance Indicators

Organizations are required to meet or exceed all established strategy performance indicators. Organizations meeting or exceeding indicators will be recognized for quality performance by CDPHE.

Performance indicators are classified into two categories:

- Indicators required by the U.S. Centers for Disease Control and Prevention (CDC) National Breast and Cervical Cancer Early Detection Program (NBCCEDP) grant. These are referred to as CDC Core Performance Indicators; and,
- Indicators required by the Colorado Department of Public Health and Environment (CDPHE). These are referred to as State Performance Indicators.

CDC Core Performance Indicators

Screening Core Performance Indicators

Screening core indicators are set by the CDC. These indicators focus on two high-risk populations: 1) rarely or never screened for cervical cancer; and 2) clients ages 50 and older for mammography. Organizations must meet the following screening core performance indicators:

- **Pap tests:** At least 20 percent of all clients *newly* enrolled for cervical cancer screening should be clients who have never been screened for cervical cancer or who have not had a Pap test in the past five years (rarely screened).
- **Mammograms:** At least 75 percent of all mammograms performed should be provided to clients who are ages 50 years and older.

Clinical Core Performance Indicators

Clinical core indicators are set by the CDC. Organizations must meet the following clinical core performance indicators for breast and cervical cases:

- **Complete Follow-up:** The percentage of abnormal cases with complete follow-up should be at least 90 percent. Follow-up is complete when cases have a final diagnosis, cancer or not cancer.
- **Time from Screening to Diagnosis:** At least 75 percent of all completed abnormal cases must be completed within 60 days or less.

State Performance Indicators

Health First Colorado BCCP Enrollment Performance Indicator (Patient/Health Navigation with Clinical Services only)

Organizations must begin the enrollment of eligible clients to Health First Colorado Breast and Cervical Cancer Prevention and Treatment Program (BCCP) within five business days of a cancer diagnosis and are then required to fax final completed paperwork to CDPHE within five business days of receiving approval for presumptive eligibility, thus completing the entire **enrollment** process in 14 days. The performance indicator is:

- Clinical Services organizations must complete the enrollment process into Health First Colorado BCCP an average of 14 days after a definitive diagnosis of cancer or pre-cancer for all enrolled clients.

Data Entry Timeliness Performance Indicator

Organizations that enter data into eCaST within 30 days can use eCaST for tracking incomplete cases and needed patient/health navigation activities. Timely data entry also allows for accurate tracking of spending. The performance indicator is:

- 90 percent of all data for all procedures must be entered into eCaST within 30 days of service being performed.

Quality Assurance Strategies

CDPHE provides feedback to organizations as part of its quality assurance and quality improvement plan. The plan has many distinct activities that relate to organization performance in the areas of quality and compliance.

Clinical chart audits
The purpose of the clinical chart audit is to ensure compliance with the clinical requirements of the Patient/Health Navigation and Clinical Services Strategy, including adherence to clinical guidelines. Clinical chart audits serve as an opportunity to determine quality of clinical services provided, evaluate clinic workflows and protocols, and solicit valuable feedback. Clinical chart audits also assist the organization in identifying areas for potential clinical quality improvement, developing a plan for making improvements and offering additional technical assistance to meet clinical requirements. Clinical chart audits are a common element of a quality assurance process. Find more information on the website.

eCaST Data Entry and Documentation

Organizations are required to manually enter encounter-level data in the Electronic Cancer Surveillance and Tracking (eCaST) web application. eCaST is a program management and public health surveillance tool. It is not an electronic health record and should not be used to gather any information beyond required data elements used for breast and cervical cancer screening and patient/health navigation surveillance. Based on data entered, agency Grant Activity Statements are generated within the eCaST application, making eCaST data entry the only way PN/CS-funded organizations can access eCaST grant funds for services to individual clients.

eCaST was developed by CDPHE in 2005. It is updated and maintained by CDPHE to meet CDC National Breast and Cervical Cancer and Early Detection Program (NBCCEDP) reporting and documentation requirements.

Data for other public health screening programs also are collected in eCaST. Client demographic data is shared across grant programs, but clinical information is only accessible by each program. It is possible that your organization may use eCaST for other public health programs. Programs using eCaST include:

- Women's Wellness Connection (Patient/Health Navigation and Clinical Services).
- Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN).

Data Collected and Reported in eCaST

All breast and cervical cancer screening procedures and funding sources must be submitted into eCaST if the organization is requesting reimbursement for Patient/Health Navigation and/or Clinical Services.

CDPHE provides forms organizations may use to collect data that must be reported via eCaST. Data must be entered within 30 days of providing each clinical service procedure to a Patient/Health Navigation or Clinical Services client. Forms can be found on the website.

Information collected on each form includes:

- **Client Profile Tool** includes age, insurance status, lawful presence and financial eligibility. Organizations are responsible for ensuring this form is filled out completely and to the best of the client's knowledge. Use of this form is optional and may be substituted by detailed documentation of the same information within the organization's records.
- **Clinical Cycle Form** can be used by organizations to document a client's medical history, clinical findings of services performed during screening visits, and recommended follow-up. Use of this form is optional and may be substituted by detailed documentation of the same information within the organization's medical records. This form does not replace documentation of procedures within the medical chart.
- **Breast and Cervical Diagnostics Forms** can be used by organizations to document diagnostic, follow-up and treatment services. Use of these forms is optional and may be substituted by detailed documentation of the same information within the organization's medical records. These forms should not be used or saved as documentation in the medical chart. It is the organization's responsibility to document this data elsewhere in the medical chart and dispose of these forms following Health Insurance Portability and Accountability Act of 1996 (HIPPA) laws.

Uses of Data

eCaST data replaces many standard reporting requirements on services to individual clients, such as in progress reports and grant invoicing. Organizations should use the eCaST application to:

- **Ensure client eligibility**
  Patient/Health Navigation and Clinical Services eligibility criteria are embedded in the eCaST application. Clients and services not meeting demographic and clinical eligibility requirements are flagged and reimbursement withheld if entered into eCaST in error. For more information on program eligibility requirements, see the Eligibility and Enrollment section of this Program Manual.

- **Monitor quality of clinical services**
  eCaST is used to monitor adherence to Patient/Health Navigation and Clinical Services clinical algorithms on individual client, organization and state levels. Abnormal breast and cervical cancer screening results per clinical algorithms are embedded in eCaST and clients requiring follow up are automatically flagged in the system, with reimbursement withheld. In addition to client-specific eCaST features, reports assessing an organization's performance on CDC core performance indicators also are available. Organizations should use eCaST in addition to other clinic processes to ensure all clients are receiving appropriate and timely diagnostic services. For more information on follow up see the Breast and Cervical Cancer Screening Procedures section of this Manual.

- **Reimburse for grant activity**
  Grant activity for the eCaST line item of the budget is assessed each month based on breast and cervical cancer screening procedures entered into eCaST. A Grant Activity Statement is

generated for organizations with complete cancer screenings containing no data entry errors. Statements are available from the eCaST application. For more information, see the Reimbursement section of this Manual.

- **Monitor grant spending and screening goals**
  eCaST has a billing dashboard feature to help organizations monitor eCaST grant fund expenditures. This feature can be used to project eCaST funds needed through the remainder of the fiscal year. CDPHE requires that organizations keep on pace to spend all eCaST grant funds allotted. This ensures CDPHE continues to receive needed funding from the CDC.

CDPHE staff members use eCaST to:

- Monitor data across all organizations to ensure the volume of data entry errors is low.
- Ensure that the clinical quality of services provided meet CDC core performance indicators.
- Ensure each organization is on pace to spend 100 percent of eCaST grant funds over the contract period.
- Identify organizations in need of eCaST funding increases or decreases.

There are limitations to eCaST data entry and use. Because eCaST is a public health surveillance tool, organizations should use their own systems or Electronic Health Records to track and/or recall clients for future screenings. Two examples of data not allowed into eCaST are: 1) data entry in text fields outside of breast/cervical cancer screening scope; and 2) data on breast or cervical cancer screenings for clients not enrolled in the Patient/Health Navigation or Clinical Services programs. eCaST report features are designed to help organizations manage eCaST grant funds effectively. However, reports and dashboard features should not be used to aggregate or analyze data for display in public presentations or reports without CDPHE approval.

Data Cleaning and Data Quality

CDPHE requires participation in a data cleaning project in mid-August and February in preparation for CDC data submissions. Organizations are required to review all cancer screenings performed over the previous one and a half years that do not meet a CDC core performance indicator or contain data errors. Organizations must review these screenings to confirm accuracy, review completeness and correct errors.

CDPHE staff members provide a list of screenings requiring review to the organization's eCaST coordinator. Typically, lists are provided via Excel spreadsheet in early to mid-August and February. Organizations are given two to four weeks to complete requested activities, depending on volume of screenings for review.

Other data cleaning and data quality projects are conducted as needed after identifying concerning data trends or at CDC's request. Projects can be focused on specific organizations or implemented statewide. Organization participation is required.

Communication regarding specific clients is primarily sent via unencrypted email. Clients are referenced by eCaST identification number alone so that no personal health information (PHI) is exposed. Fax, encrypted email and file transfer protocol sites may be used when CDPHE staff members must communicate PHI. Please use the same secure means to communicate PHI with CDPHE staff members. Information shared with CDPHE is confidential.

eCaST Location and Software Requirements

The eCaST application is located on CDPHE's Health Informatics Portal.

Organizations do not need to install additional software beyond a web browser. eCaST data entry is a contract requirement. It is important that eCaST users at your organization have access to an eCaST-supported web browser. eCaST runs most efficiently on Google Chrome (download here); however, Mozilla Firefox and Internet Explorer version 9+ also are supported. **Note that eCaST does not function on, and is not supported on, Internet Explorer version 8 or earlier versions.**

Accessing eCaST

All staff members needing new access to eCaST are required to complete the eCaST Basics Video Training session before they are given access. The eCaST Basics Video Training session consists of a set of modular videos demonstrating proper use of eCaST and a subsequent set of sample data entry tasks to be completed in a test environment. The eCaST Basics Training regimen can be taken at any time throughout the year. Staff members must coordinate their training with the data coordinator.

When an existing eCaST user no longer needs access for data entry, an organization must report this change to CDPHE within 15 days so that the user's account can be deactivated.

Data Security and Confidentiality

All eCaST users are required to agree to the CDPHE Data Use, Security and Confidentiality agreement prior to accessing the eCaST application. This agreement is signed by the user electronically when enrolling or annually renewing access to eCaST. A copy of this agreement and CDPHE's security policy can be found here.

Authority for Data Collection

CDPHE receives authority to collect client data through the CDC's NBCCEDP and Colorado Revised Statute 25-6-103.

The statement of work for contracts includes the requirement for collecting and submitting breast and cervical cancer screening data.

CDPHE is not a HIPAA entity. According to Title 45 CFR 164.512, however, "A covered HIPAA entity may disclose protected health information to a health oversight agency for oversight activities authorized by law." CDPHE can receive protected health information as it relates to health oversight activities. Additional information regarding CDPHE and the HIPAA privacy rule language can be found in your organization's contract with CDPHE.

Agency Reimbursement

Organizations funded for Patient/Health Navigation Strategy with or without the Clinical Services Strategy will be reimbursed per cancer screening completed and entered into eCaST based on the reimbursement schedule below. Payment for services is based on the date the final data is entered into eCaST to complete or administratively close a case.

The bundles for breast and cervical cancer screening services make up the Bundled Payment System (BPS). Organizations are only reimbursed for patient/health navigation and clinical services when requested within eCaST. For example, an organization may provide navigation to completion of an

office visit and mammogram and may request reimbursement for each of the following four elements as needed: office visit including breast history, mammogram, navigation through office vision, and navigation to complete the mammogram.

Clinical Services reimbursement rates are based on Medicare rates for procedures allowable within a given bundle. Rates are set based on current Medicare CPT code rates at the beginning of each fiscal year.

Reimbursement for breast cancer screening procedures performed may include:

Definition of activities	Clinical Services reimbursement	Patient/Health Navigation reimbursement
Navigation and completion of an office visit with breast health education and CBE (as needed).	$45: Office visit, including breast history, must be completed for breast services. May include a CBE. • Breast education must be provided if CBE not performed.	$15: Patient/health navigation services through completion of office visit.
Navigation and completion of initial mammogram.	$140: Initial mammogram.	$30: Patient/health navigation from mammogram referral through completion of initial mammogram.
Navigation and completion of breast diagnostic imaging.	$310: Additional mammogram, ultrasound and/or surgical consult.	$60: Patient/health navigation from abnormal screening results, including initial mammogram through completion of diagnostic testing and treatment referral as needed.
Navigation and completion of Invasive breast diagnostic testing.	$995: Invasive diagnostic testing.	

Reimbursement for cervical cancer screening procedures performed may include:

Definition of activities	Clinical Services reimbursement	Patient/Health Navigation reimbursement
Navigation and completion of office visit with cervical health education and pelvic exam (as needed).	$45: Office visit, including cervical history, must be completed for cervical services. • May include a pelvic exam. Cervical education must be provided if pelvic exam not performed.	$15: Patient/health navigation services through completion of office visit.
Navigation and completion of initial cervical screenings.	$30: Pap test. $55: HPV.	$30: Patient/health navigation during office visit through completion of Pap with or without HPV (as needed).
Navigation and completion of invasive cervical diagnostic testing and diagnosis information.	$260: Invasive diagnostic testing.	$60: Patient/health navigation from abnormal screening results through completion of diagnostic testing and treatment referral as needed.

Patient/Health Navigation and Clinical Services BPS Reimbursement Covers

Organizations are paid for services to individual clients according to the fiscal year's BPS Chart after all information on a client's cycle has been entered completely and accurately into eCaST. Organizations accept this reimbursement as payment in full for these services. Reimbursement from eCaST is expected to also cover costs associated with:

- Enrollment of clients into Patient/Health Navigation and Clinical Services.
- Breast and cervical cancer screening procedures as outlined in the CPT Code List (Eligible uninsured/underinsured clients only).
- Patient/health navigation services to individual clients.
- Notification to clients of procedure results.
- Assistance scheduling appointments.
- Entry of all information into eCaST.
- Health First Colorado's BCCP enrollment (Eligible uninsured/underinsured clients only).
- Personnel time to provide the above items.

Clinical Services clients must not be billed for services described in the CPT Code List. Moreover, should there be a difference between an organization's standard rate for a given service and the Clinical Services rate for that service, the difference is not payable by CDPHE and must not be billed to the client. If services not on the CPT Code List are provided, organizations may bill the client for these services. However, clients must be notified and advised of the costs before services are provided.

Clients requiring multiple breast and cervical screening services (i.e. clients with short term follow-up or clients returning with new cancer symptoms) within the fiscal year may be entered and reimbursed through eCaST.

Adjustments to Reimbursements through eCaST

When there is a difference between what an organization was paid earlier in the contract period and the current eCaST balance, funds will be adjusted (credited or debited) on the agency's Grant Activity Statement. Adjustments may occur in the following circumstances:

- Client information is updated, demonstrating ineligibility for Patient/Health Navigation and/or Clinical Services.
- Services are added or removed from eCaST that change the case status from closed to open.
- Services added to or removed from eCaST that cause the reimbursement amount to change.
- Data changed by data entry staff from a known value to a missing value.
- Reimbursement made in error for duplicate clients identified.
- CDPHE places a case on hold or administrative override because the case does not meet contractual requirements.

Organizations may not be required to change the funding source for services previously rendered, even if the new coverage is retroactive (for example, Health First Colorado). While it is not a requirement to change the funding source in eCaST, it also is not allowable to charge the same procedure to two funders (for example, CDPHE and Health First Colorado). Organizations that choose to retroactively charge another funder for services previously paid by CDPHE must change the funding source in eCaST from WWC to the new funding source.

Reimbursement through eCaST

Grant Activity Statements are generated the 15th of each month or the first business day after the 15th, except for the first month of the fiscal year (July) on the organization's behalf according to services entered in eCaST. All clients with complete and accurate clinical and follow-up data in eCaST at that time will be included in the billing cycle. The final Grant Activity Statement is generated through eCaST 30 days after the end of the fiscal year (i.e., 30 days after June 29).

Reimbursement checks are produced by and mailed from the state controller's office, not the Colorado Department of Public Health and Environment. Each check received will include a payment voucher number. This number also is listed on each Grant Activity Statement (the invoice generated in eCaST) so that organizations can verify which clients are associated with checks received.

Tracking eCaST Budgets

Each organization receives an eCaST funding amount that it can use to provide services under the Patient/Health Navigation and/or Clinical Services strategy each fiscal year. Once an organization's total eCaST budget amount has been reached, CDPHE will not pay for any additional expenses incurred by the organization. Organizations are encouraged to contact CDPHE staff to determine if there is a possibility to receive additional eCaST funds.

Organizations that are under-spent in their eCaST budgets may have funds taken back and reallocated to other organizations at any time during the contract period.

The Budget Tracking Report is available in eCaST as a tool for organizations to monitor their budget progress during the fiscal year. The Budget Tracking Report includes the percent of eCaST funds expended, year-to-date total paid, and average costs per screening as well as average cost per woman served. The budget reports are updated during the mid-month billing reimbursement process. Organizations are notified monthly when billing reports are available.

Changes to the eCaST line item of the budget require written approval from CDPHE staff.

Reimbursement for non-eCaST Budget Costs

The non-eCaST budget items for the Patient/Health Navigation and Clinical Services Strategies are cost reimbursable, meaning the funded organization must provide the service or purchase the item to be reimbursed by CDPHE through monthly submission of a CDPHE Reimbursement Invoice Form. At the time of a grant award, a customized invoice will be provided. Invoices are due 45 days after the completion of the month. For example, a July invoice is due no later than Sept. 15. Organizations must submit a $0 invoice if not requesting funds for a month.

Organizations must not use non-eCaST funds to pay or request reimbursement for personnel time, supplies, and operating and travel costs that are attributable to individual clients and already reimbursed through the Bundled Payment System described above.

The list of allowable purchases for Patient/Health Navigation and Clinical Services supplies and operating expenses is posted on the Cancer Prevention and Early Detection website. Organizations wishing to purchase items that are not on this list must email their CDPHE Program Coordinators to request approval and provide justification of how the cost relates to Patient/Health Navigation and/or Clinical Services.

Subcontracting – Clinical Services Strategy Only

Initial screening services (Pap, pelvic and clinical breast exam) for uninsured/underinsured clients through the Clinical Services Strategy must be carried out by the funded organization. Diagnostic services for uninsured/underinsured clients through the Clinical Services Strategy may be carried out through subcontracts with other providers (See the Breast and Cervical Cancer Screening Procedures section). When an organization delivers covered breast and cervical cancer screening procedures by referring clients to another provider, a subcontract or memorandum of understanding (MOU) must be in place between the two organizations. This agreement must incorporate a mechanism for payment.

Subcontracting Requirements

Subcontracts must be secured with local providers to the extent possible. Clients should not be required to travel more than 60 miles for any service, unless a highly specialized service (breast surgery, stereotactic biopsy, etc.) is required and is not available at any facility within that radius. Any subcontracts for services beyond 60 miles must receive CDPHE staff approval.

In addition, Clinical Services clients and CDPHE must not be billed or made responsible for any costs associated with services outlined on the Current Procedural Technology (CPT) Code List. If services not on the CPT Code List are provided, subcontractors may bill the client for these services. However, clients must be notified and advised of the costs before services are provided. CDPHE updates the CPT Code List annually based on information found on the Centers for Medicare and Medicaid Services website.

CDPHE does not work directly with subcontractors of the organization. Communicating with subcontractors is the responsibility of the organization.

Typical Services Subcontracted

Clinical Services organizations are authorized to subcontract all services except Pap, CBE and pelvic exam. Typical services for which organizations subcontract include:

- Mammography services.
- Surgical services.
- Pathology services.
- Diagnostic procedures.
- Other specialty services.

A subcontractor is subject to all of the terms and conditions of the Clinical Services organization's contract. Additionally, the Clinical Services organization remains ultimately responsible for the timely and satisfactory completion of all work performed by any subcontractor(s) under the contract. The Clinical Services organization must maintain, at a minimum, an MOU or other binding contractual agreement. The Clinical Services organization must provide a list of all current subcontracts to CDPHE within 15 days of executing the contract and report all subcontractor changes to CDPHE within 15 days of occurrence. Organizations are required to verify subcontractors in eCaST at the start of each fiscal year.

Subcontracting Basics

It is each Clinical Services organization's responsibility to ensure that its subcontracts or MOUs are reviewed by its legal counsel.

Subcontracts should be signed by both parties, outline specific roles and responsibilities, and ensure that all financial obligations are defined and other terms/conditions included.

At a minimum, the following elements should be incorporated into an agreement:

- General description of the project, including an outline of the specific roles and responsibilities.
- Deliverables (specific screening services to be provided).
- An agreement to screen Clinical Services clients referred to them at current Medicare rates specified in the current CPT code list.
- Signatures of both parties.

Referral network – Patient/Health Navigation Strategy for insured clients

Organizations funded for Patient/Health Navigation of insured clients must have a referral network for additional required services such as mammograms, ultrasounds, breast biopsies, colposcopies, Loop Electrosurgical Excision Procedures (LEEP), Magnetic Resonance Imaging (MRI) or other approved breast or cervical diagnostic services if they are not being directly provided by the Organization.

Organizations must not subcontract for patient/health navigation services. Activities commonly done by subcontractors or referral providers, such as reminder calls or client notification of results, are acceptable.