Breast & Cervical CANCER EARLY DETECTION Program of Alabama

ALABAMA BREAST AND CERVICAL CANCER EARLY DETECTION PROGRAM

PROVIDER MANUAL

Revised June 2016

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The following materials are located on the ABCCEDP website: http://www.adph.org/earlydetection

- **General Program Information**
  - Program Summary
  - Eligibility Criteria
  - Annual Income Eligibility Guidelines
  - Reimbursement Rate Table (updated annually)
  - Med-IT Website Enrollment Instructions
  - Electronic Copy of Provider Manual
  - Regional Coordinator Contact List
  - Regional Coordinator Map

- **Medicaid Treatment Program**
  - Treatment Referral Form
  - Treatment Program Summary
  - Treatment Eligibility Criteria

- **Contractual**
  - Provider Contract
  - Contract Attachments
  - Contract Document Checklist

- **Data and Billing**
  - Mammography Voucher
  - Screening Form
  - Cervical Diagnostic Follow-up Form
  - Breast Diagnostic Follow-up Form
  - Informed Consent Form
  - Health Insurance Claim Form
  - Breast Authorization Form

Section 1: Program Summary

Alabama Breast and Cervical Early Detection Program (ABCCEDP) Overview:

The Alabama Breast & Cervical Cancer Early Detection Program (ABCCEDP) is a statewide program of the Alabama Department of Public Health (ADPH) aimed at providing breast and cervical cancer *screening and diagnostic services* to women who meet certain age, income and insurance coverage guidelines.

Title XV of the Public Health Services Act, known as the Breast and Cervical Cancer Mortality Prevention Act of 1990" (Public Law 101-354) established a program of grants to states for the detection and control of breast and cervical cancer. The grants are awarded to states via a cooperative agreement by CDC through a competitive application process. The purpose of the funding is to provide early detection screening and referral services for breast and cervical cancers with emphasis placed on women age 40 and older who are uninsured, under insured, of minority status and less than 200 percent of the federal poverty level.

The key to reducing illness and death from breast and cervical cancer is early detection by widespread use of screening and timely follow-up with treatment if necessary. Routine screening can detect many of these cancers at early stages when more treatment options are available and the likelihood of survival is improved. Nearly all cervical cancer deaths and more than 30 percent of breast cancer deaths could be prevented.

Clinical Guidelines:

The ABCCEDP clinical guidelines are based on a combination of federal law and regulations imposed by the Centers for Disease Control and Prevention (CDC) and with recommendation from the ABCCEDP Medical Advisory Board.

Purpose of Provider Manual:

The purpose of the provider manual is to provide standardized guidelines for breast and cervical cancer screening services for eligible Alabama Breast and Cervical Cancer Early Detection Program (ABCCEDP) participants.

Each screening provider should have a designated staff member who is responsible for receiving ABCCEDP memorandums, programmatic updates, and for distributing this information to the appropriate staff**.** Screening providers must adjust to changes in program guidelines. Each screening provider must allow in-service training to existing staff members and to new employees to assure program compliance.

Patient Enrollment:

All women must be enrolled in the ABCCEDP prior to receiving a screening. Eligibility information and patient demographics will be entered and a tracking number will be assigned to the patient. This tracking number must be written on all ABCCEDP forms utilized by the program. Provider web enrollment guide is available on the ABCCEDP website (http://adph.org/early detection/) under forms.

Patient Rights:

Confidentiality of Patient Information

- ABCCEDP health care providers will be required to:
- Protect the use or disclosure of any woman's medical or social information of a confidential nature.
- Consider medical services to and information contained in medical records confidential.
- Disclose the woman's medical records to contracted ABCCEDP physicians or medical facilities accepting the woman.
- Disclose the woman's medical records to the ABCCEDP state office.
- Disclose in summary or other form, information which does not identify individuals or providers, if such information is in compliance with applicable federal and state regulations, and the exchange of individual medical record information is in keeping with established medical standards and ethics.

Informed Consent

- An informed consent documenting the woman's consent to receive breast and cervical cancer screening services must be signed prior to her receiving any ABCCEDP services.
- The consent form must be signed by the patient. The signed form must be kept in the woman's permanent medical record.
- This form can be printed from the program web page www.adph.org/earlydetection.

Section 2: Screening Eligibility Guidelines

Eligibility Criteria for Screening

The ABCCEDP will provide breast and cervical cancer screening services to women who meet the following eligibility criteria. Services must be provided by an ABCCEDP participating provider.

All ADPH county health department clinics throughout the state are participating providers, as well as approximately 400 hospital, outpatient diagnostic centers and private physicians. The screening provider determines a woman's eligibility by applying the following guidelines:

Applicant Eligibility guidelines

- Women who meet current **age eligibility guidelines.** See current age guidelines at www.adph.org/earlydetection
- Women who are uninsured or underinsured
  Definition of underinsured is:
  - Have health insurance which does not cover ABCCEDP services, or
  - Have health insurance that does not cover reimbursement of the full amount of the established fees for covered services, or
  - Have a deductible or coinsurance amount which the women cannot afford to pay, or

    - Have Medicare Part A ONLY
- Transgender women (male-female), who have taken or are taking hormones, may be eligible to receive breast cancer screening and diagnostic services. To be eligible the patient must be:
    - Age 50-64 with one of the following additional risk factors:
        - BMI > 35
        - Positive family history of breast cancer
        - Estrogen and Progestin use > 5 years
    - Note: Routine annual screening is not recommended for this group. Preventive care recommendations can be found at http://transhealth.ucsf.edu/trans?page=protocol-screening#S2X

- Women who meet Income Eligibility Guidelines
  Household income must be at or below 200% of the Federal Poverty Guidelines. These income guidelines are updated annually by the Department of Health and Human Services (DHHS). Household income includes all sources of income for ALL household members including disability and child support payments. Proof of income is not required. The woman's declaration statement is sufficient. See current income guidelines at www.adph.org/earlydetection

- Men are not eligible for ABCCEDP or any National Breast and Cervical Cancer Early Detection Program according to the law establishing the program. It is recognized that while men are at some risk of developing breast cancer, the percentage is very low (less than 1%) compared to women

Eligibility questions or concerns

For additional questions or concerns, contact your ABCCEDP Regional Coordinator. An ABCCEDP Regional Coordinator list which includes the coordinator's name and the counties they cover can be found on the ABCCEDP website at: www.adph.org/earlydetection.

Breast & Cervical EARLY CANCER DETECTION Program of Alabama

PROVIDER CONTRACTING

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Section 3: Provider Contracting Process

Provider Contracts

All providers must execute an approved Public Health contract document PRIOR to the provision of services. Contracts are for two year periods of time, expiring odd numbered years on June 29th.

Required Documents

In addition to the executed contract, the following must also be provided:

- Disclosure Statement
- Applicable Check List (physician, anesthesiologist, mammogram facility or laboratory)
- Copy of all physician and certain licensed healthcare professional licenses
- Copy of certain facility licenses
- Copy of current fee schedule on practice letterhead
- W-9 Form

E-Verify

All providers must enroll in the Department of Homeland Security's E-Verify Program at http://www.dhs.gov/e-verify. You will receive a MOU which is generated when you enroll in the E-Verify Program, bearing the number assigned to that MOU by the U.S. Department of Homeland Security. **A complete copy of that MOU must be submitted.**

Certificate of Compliance

A certificate of compliance must be completed in its entirety, signed, and witnessed

Acknowledgement of Receipt (Whistleblower Protection)

An acknowledgement of Receipt (Whistleblower protection) must be completed in its entirety, and be signed and dated

Provider Checklist and Contractor/Sub-Contractor Forms

These forms must be completed in their entirety.

- Some providers do not include their facility on the Contractor/Sub-Contractor Form because they think this form is completed only if they have sub-contractors. Please include your facility's information on this form as well.
- On the Provider Checklist Form, please answer all appropriate questions, such as:
  - 1 – Are patients billed separately for lab procedures?
  - 2 – Are services and facilities accessible to the disabled?
  - 3 – Are your services billed as global, technical, or professional fees or a mixture?

Required Regional Coordinator Notification Regarding Contracts

Providers MUST notify the Regional Coordinator when any of the following takes place:

- The federal tax identification number (FEIN#) changes
- Changes in practice name, physical or mailing address, phone or fax numbers

and contact personnel
- If billing methodologies change from global, technical or professional or when billing methodologies are different for selected procedures
- When the mailing address for the receipt of payments changes
- When physicians leave or join a practice to include a copy of the current license
- Upon expiration of any facility, physician or licensed healthcare professional license expiration, a copy of the renewed license must be faxed to the Regional Coordinator. Note: All physician licenses in Alabama expire each December 31. Registered nurse licenses expire every other year on December 31(even years). Mammogram facility certifications expire on different schedules

Section 4: Provider Responsibilities

Primary Provider Screening Requirements

Program Requirements:

Alabama Breast and Cervical Cancer Early Detection Program Providers must:

- Maintain current and applicable federal and/or state licenses
- Agree to accept the program approved reimbursement fee as payment in full for services rendered. That reimbursement, by law, cannot be over the current Medicare reimbursement rate

Screening Requirements:

Alabama Breast and Cervical Cancer Early Detection Program Providers must:

- Provide breast and cervical cancer screening services for women who meet eligibility requirements per current screening guidelines found later in this manual
- Develop referral resources for diagnostic and treatment services not funded by the ABCCEDP
- Ensure appropriate and timely follow-up for all ABCCEDP participants according to CDC guidelines
- Provide patient education
- Provide education and community outreach by working with local partners

Patient Services

To enroll a patient as a participant in the ABCCEDP, the screening provider must:

- Determine eligibility based on income, age, and insurance status
- Obtain a tracking number through the ABCCEDP web based enrollment site @ www.adph.org/earlydetection
- Obtain a signed ABCCEDP informed Consent/Release of Information Form (found on ABCCEDP web site)
- Complete the screening form (found on the ABCCEDP website) for each woman and submit to the appropriate Regional Coordinator along with billing or appropriate HCFA/UB form
- Provide required screening and educational services

Patient Education

Providers are required to provide women with information and educational services on the early detection of breast and cervical cancer. The purpose of the education component is to provide women with the information necessary to:

- Understand the screening procedures used in the detection of breast and cervical cancer
- Motivate the woman to comply with recommended guidelines for screening as it relates to present appointment and future screening practices
- Provide education and information appropriate for the woman's age, lifestyle, educational level, and ability to understand. This instruction should be documented in the woman's record and she should be allowed an opportunity to ask questions and verbalize her understanding of the educational information presented

Record Keeping

- The ABCCEDP requires that a copy of all ABCCEDP reimbursed screening and diagnostic reports be placed in the patient's permanent medical record maintained by the primary provider
- The provider must document all education they provided to the woman
- The provider must establish a system for tracking women that notifies her when routine screening and/or follow-up is due

Outside Referral

Patients should be referred in accordance with clinical guidelines to ABCCEDP contracted providers for any or all of the following services:

- Mammography
- Breast Ultrasound
- Colposcopy
- Surgical or GYN consult
- Fine Needle Aspiration
- Breast Biopsy

Referral for Abnormal Results

The primary screening provider who provides the CBE, pelvic examination, or Pap smear is responsible for **appropriate and timely follow-up** for diagnostic and treatment services. The primary screening provider is responsible for:

- Counseling each woman who has abnormal tests or exams and documenting this visit.
- Referring or providing any additional diagnostic work-up and treatment needed. Some diagnostic services are not funded by the ABCCEDP. **No treatment services are funded by the ABCCEDP**
- Ensuring the woman has completed the recommended follow-up
- Documenting attempts to contact women who need follow-up
- Recording the woman's response to the provider's contact
- Providing the Regional Coordinator with information regarding the outcome of the woman's diagnostic tests and treatment needed **within 60 days** of scheduled follow-up appointments
    - If this information is not received the Regional Coordinator will:
        - Make 2 attempts to get the information from the primary provider

- Contact referral provider and/or the woman for missing information
- Notifying the Regional Coordinator if the woman needs assistance to identify and access available community resources beyond provider efforts

Tracking and Follow-Up

Each health care provider and facility must:

- Utilize a tracking protocol that assures effective communications with the woman, health care providers, and laboratory personnel
- Maintain a record of Pap smears, HPV testing, and mammograms done to ensure results are received in a timely manner
- Address barriers that cause difficulty with recommended follow-up
- Facilitate proper follow-up for women with abnormal screening results, as well as annual re-screen
- Maintain a screening system to notify women as screenings are due

Missed Abnormal Follow-up Appointments

- Providers **must** contact the woman for missed appointments for diagnostic or treatment procedures. These should begin with a phone call, then a letter or post card, and finally a certified letter. This would usually occur over a 30-60 day time period
- If after two months from the abnormal screening results, the woman does not respond to **documented** repeated phone contacts and/or a certified letter to schedule additional diagnostic procedures, the work-up disposition will be entered in the ABCCEDP data system as one of the following:
  - **Lost to follow-up** - if the woman cannot be contacted via phone, post card, or certified letter
  - **Work-up refused** - if the woman refuses additional diagnostic tests or does not show twice for scheduled follow-up appointments
  - The screening cycle will be closed at that time. A woman lost to previous follow-up attempts shall not be denied future screening services

It is the screening provider's responsibility:

- To notify the Regional Coordinator if there is a change in their FEIN#, mailing address, or license status
- To notify the Regional Coordinator when a change in billing methodologies from global, technical, or professional takes place for any procedure
- To provide Regional Coordinator with copies of new or renewed licenses for the facility, physicians and selected healthcare professionals
- To maintain a re-screening system to notify the woman as cancer screenings become due

Referral Provider Requirements

All referral and consultant providers must agree to accept the ABCCEDP approved reimbursement fee as payment in full for services rendered.

Mammography Provider

All mammography providers for the ABCCEDP **Must**:

- Be accredited by the ACR and certified by the FDA and in compliance with the MQSA
- Require their radiologists to record mammography findings using the ACR Breast Imaging Reporting and Data System (BI-RADS)
- Maintain records and films of ABCCEDP women according to MQSA requirements
- Agree to accept the program approved reimbursement fee as payment in full for services rendered for ABCCEDP approved CPT codes as indicated on the reimbursement table

All mammography providers must agree to provide upon referral:

- Screening mammograms for women over 40
- Diagnostic mammograms, if indicated
- Ultrasound, if indicated
- Other related diagnostic procedures which are approved for reimbursement by the ABCCEDP, if available and indicated
- Appropriate and timely follow-up for all ABCCEDP patients according to MQSA guidelines

Mammography Provider's Reporting Requirements

To receive reimbursement the facility must submit to the Regional Coordinator the following:

- The original mammography voucher
- An invoice or bill with the patient's name
- The report of the screening or diagnostic exam performed
- The Health Insurance Claim Form (HIFA 1500 or the UB 92 for facilities)

It is the Mammography Provider's Responsibility:

- To notify the Regional Coordinator if there is a change in their FEIN#, mailing address, or license status
- To notify the Regional Coordinator when a change in billing methodologies from global, technical, or professional takes place for any procedure
- To provide Regional Coordinator with copies of new or renewed licenses for the facility, physicians and selected healthcare professionals
- To maintain a re-screening system to notify the woman as screenings become due.

Cytology Laboratories

- Any laboratory that performs procedures either directly, under contract or indirectly (under a global contract with a contracted provider) for ABCCEDP patients, must be currently certified under CLIA
- All laboratory providers will require the pathologists to record Pap smear findings using the Bethesda System
- All providers must agree to accept the program approved reimbursement fee as payment in full for services rendered for ABCCEDP approved CPT codes as indicated on the reimbursement rate table

Laboratory Reimbursement Requirements

In order to receive reimbursement, the lab provider must submit all procedures performed to the Regional Coordinator by the 15th of each month.

It is the laboratory provider's responsibility:

- To notify the Regional Coordinator if there is a change in their FEIN #, mailing address, license status
- To notify the Regional Coordinator when a change in billing methodologies from global, technical or professional takes place for any procedure
- To provide the Regional Coordinator with copies of new or renewed licenses for the facility, physicians and selected healthcare professionals

Colposcopy Provider

ABCCEDP Colposcopy Providers must:

- Be a physician, PA, or a CRNP who is certified in performing colposcopy and currently licensed in the State of Alabama
- Must agree to accept the program approved reimbursement fee as payment in full for services rendered for ABCCEDP approved CPT codes as indicated on the reimbursement table

Colposcopy Reporting Requirements

The colposcopy provider must submit copies of the following to the referring screening provider and the Regional Coordinator by the 15th of the month for procedures performed in the prior month:

- Completed Cervical Diagnosis and Follow-Up Form.
- Report of pathological findings (when biopsy and/or ECC is performed).
- Progress note showing date of colposcopy
- Completed HCFA 1500 or UB 92

It is the colposcopy provider's responsibility:

- To notify the Regional Coordinator if there is a change in their FEIN #, mailing address, license status
- To notify the Regional Coordinator when a change in billing methodologies from global, technical or professional takes place for any procedure
- To provide the Regional Coordinator with copies of new or renewed licenses for the facility, physicians and selected healthcare professionals
- To maintain a re-screening system to notify the woman as screenings become due

Consultation Providers

All consultation providers must agree to accept the program approved reimbursement fee as payment in full for services rendered for ABCCEDP approved CPT codes as indicated on the reimbursement table.

Consultation Reporting Requirements

The consultant must submit to the referring provide and the Regional Coordinator:

- Completed Breast or Cervical Diagnosis and Follow-Up Form with recommendations
- Report of pathological findings and recommendations
- Completed HCFA 1500 or UB 92

It is the consultant provider's responsibility:

- To notify the Regional Coordinator if there is a change in their FEIN #, mailing address, license status
- To notify the Regional Coordinator when a change in billing methodologies from global, technical or professional takes place for any procedure
- To provide the Regional Coordinator with copies of new or renewed licenses for the facility, physicians and selected healthcare professionals
- To maintain a re-screening system to notify the woman as screenings become due

Breast & Cervical CANCER EARLY DETECTION Program of Alabama

SCREENING

AND

DIAGNOSTIC

SERVICES

Section 5: Screening and Diagnostic Services

Screening Visit Guidelines
The woman must meet eligibility guidelines as described on page 4 and 5 of this manual.

Routine Comprehensive Office Visit (CPT 99203)
One comprehensive visit every 12 months
Services include:

- Yearly clinical breast exam (CBE)
- Yearly screening mammogram
- Routine Cervical Cancer Screening
  (Pap smear every 3 years or Pap smear/HPV every 5 years)

Partial Screening Visit
Services include (cervical cancer screening only **OR** clinical breast exam only)

- New patient partial screening (CPT 99202): Pelvic exam with Pap smear or Pap smear/HPV, **OR** clinical breast exam
- Established partial screening (CPT 99212): Pelvic exam with Pap smear or Pap smear/HPV, **OR** clinical breast exam

Follow-up visit (CPT 99212)

- Follow-up Pap smear and/or HPV **OR** follow-up clinical breast exam
- ABCCEDP will reimburse for a maximum of 3 follow-up visits. If additional visits are needed, written justification must be provided and approval must be given. Copies of medical records may be needed to support justification of follow-up visit

See the reimbursement table for other screening and diagnostic services and CPT codes

NOTE: By law, ABCCEDP services are free to the patient and women should not be charged any fees for program services at any time.

Section 6: Breast Cancer Screening and Diagnostic Services

Clinical Breast Exam Visit

- ABCCEDP will reimburse a maximum of 3 repeat CBE visits in any 12 month period
- ABCCEDP will not reimburse for any procedures related to breast implants other than those related to breast cancer screening/diagnosis
- No reimbursement will be paid for cytology analysis of a breast discharge

Mammogram/Ultrasound Screening Diagnostic Guidelines

- A CBE needs to be done on all women prior to having a mammogram. A CBE should be done as close to the mammogram date as possible, but must have been performed in the last 6 months
- One screening mammogram will be reimbursed during a 12 month period. Referrals for mammograms should be one year apart, but in no case less than 10 months

- If the woman has an abnormal CBE she should be scheduled for a diagnostic mammogram instead of a screening mammogram
- No more than 3 diagnostic mammograms will be reimbursed in a 12 month period
- A woman who by virtue of symptoms or physical findings, and is considered to have a substantial likelihood of having breast disease is eligible to be referred for a **diagnostic mammogram and/or ultrasound** if she meets age, income and insurance eligibility
- An ultrasound of the breast will be reimbursed for a woman whose mammogram or CBE indicates a need for one
- A woman due for screening who has breast implants should always have a diagnostic mammogram. Four views instead of two are usually taken

Breast MRI Guidelines (Requires Prior Authorization) – A prior authorization form must be completed and forwarded to the Regional Coordinator and approval must be received before an MRI will be reimbursed.

ABCCEDP will cover MRI for high risk women ages 40 – 64 who meet one of the following criteria:

- A known BRCA 1 or BRCA 2 gene mutation (documentation/proof required)
- A 1st degree relative (parent, brother, sister, child) who has a BRCA 1 or BRCA 2 gene mutation (documentation/proof required)
- A lifetime risk of 20-25% or greater as defined by risk assessment models such as BRCAPRO (copy of risk assessment required)

In Addition, the MRI:

- Must be in conjunction with a mammogram
- Must be ordered by a surgeon
- Must be done at a facility with dedicated breast MRI equipment and these facilities must have the ability to perform MRI-guided breast biopsies

Breast Screening and Diagnostic Results

Breast Cancer Screening Results

Normal Results (CBE and Mammogram)

When the CBE and mammogram are both normal, it is the provider's responsibility to:

- Have a reminder system in place which allows the screening provider to notify the woman prior to the date due for routine annual re-screen

Abnormal Results (CBE or Mammogram)

It is the responsibility of the screening provider to:

- Notify the woman of results and establish a system for tracking these women for appropriate and timely follow-up for diagnostic services and treatment as needed
- Plan and implement a diagnostic work-up so that the time from the screening mammogram or CBE (whichever occurs first) to final diagnosis is no more than 60 days.
- Refer to a surgeon any abnormal CBE or abnormal mammogram (BI-RAD 4 or 5)
- Maintain, as a part of the woman's permanent medical record documentation of all test results, related education, resulting recommendations and /or referrals with dates.

Normal/benign diagnostic mammogram with abnormal CBE

A mammogram alone is not an adequate follow-up for an abnormal CBE.
CDC requires that the patient also has one of the following:

- Repeat CBE
- Ultrasound
  and/or
- Surgical consult

Surgeon Referral/Consultation Visits

For a surgeon referral to be reimbursed, one of the following must be present:

- An abnormal CBE suspicious for cancer (regardless of mammographic findings) to include:
  - Palpable mass
  - Bloody or serous discharge – no green, black or white discharge
  - Nipple or areolar scaliness, retraction, or skin dimpling
- An abnormal mammogram with result of BI-RAD 4 or 5
- An abnormal ultrasound suspicious for cancer

Breast Diagnostic Services

- Breast biopsies: A biopsy may be reimbursed to a facility and a surgeon
- Stereotactic: A stereotactic procedure may be reimbursed if ordered by the surgeon or radiologist
- Breast Cytology: ABCCEDP will NOT pay for cytology testing of breast discharge or for medical work-up for galactorrhea
- Ductograms: ABCCEDP will reimburse for ductogram when the following criteria is met:
  - Must have spontaneous bloody nipple discharge
  - Must have had a mammogram and ultrasound in which nothing abnormal was found
  - Must be ordered by a surgeon
- A mass in the tail of Spence is appropriate for further medical referral
- Gamma Imaging is **NOT** a reimbursable service

Adequacy of follow-up for women with abnormal screening results

- A woman whose breast cancer screening was abnormal or suspicious must receive appropriate diagnostic procedures to arrive at a final diagnosis, and
- Women in whom breast cancer has been diagnosed must be referred for appropriate treatment.

Timeliness of follow-up for women with abnormal breast screening results

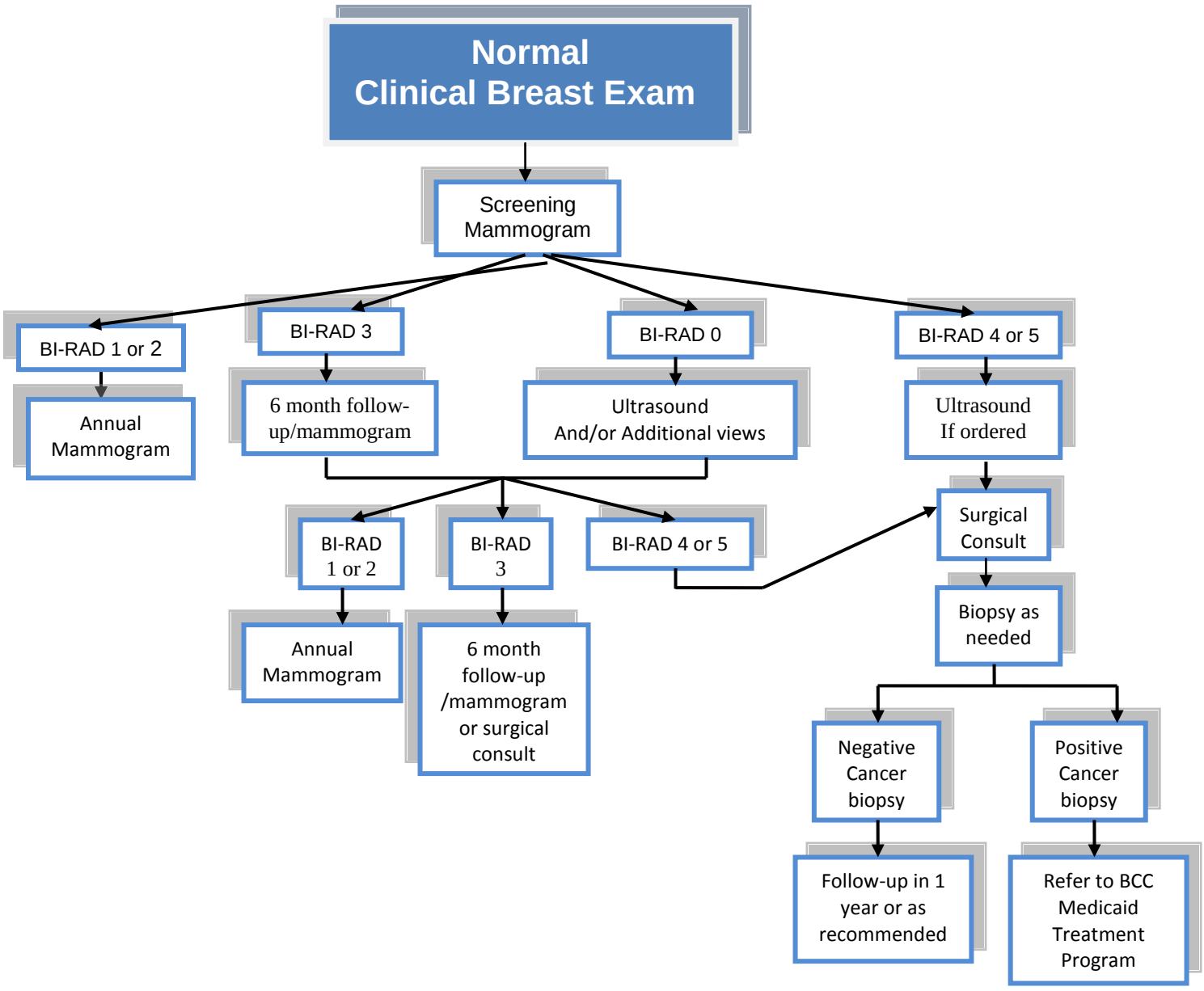
- The interval between initial screening and diagnosis of abnormal breast screenings should be 60 days or less
- The interval between diagnosis and initiation of treatment for breast cancer should be 60 days or less

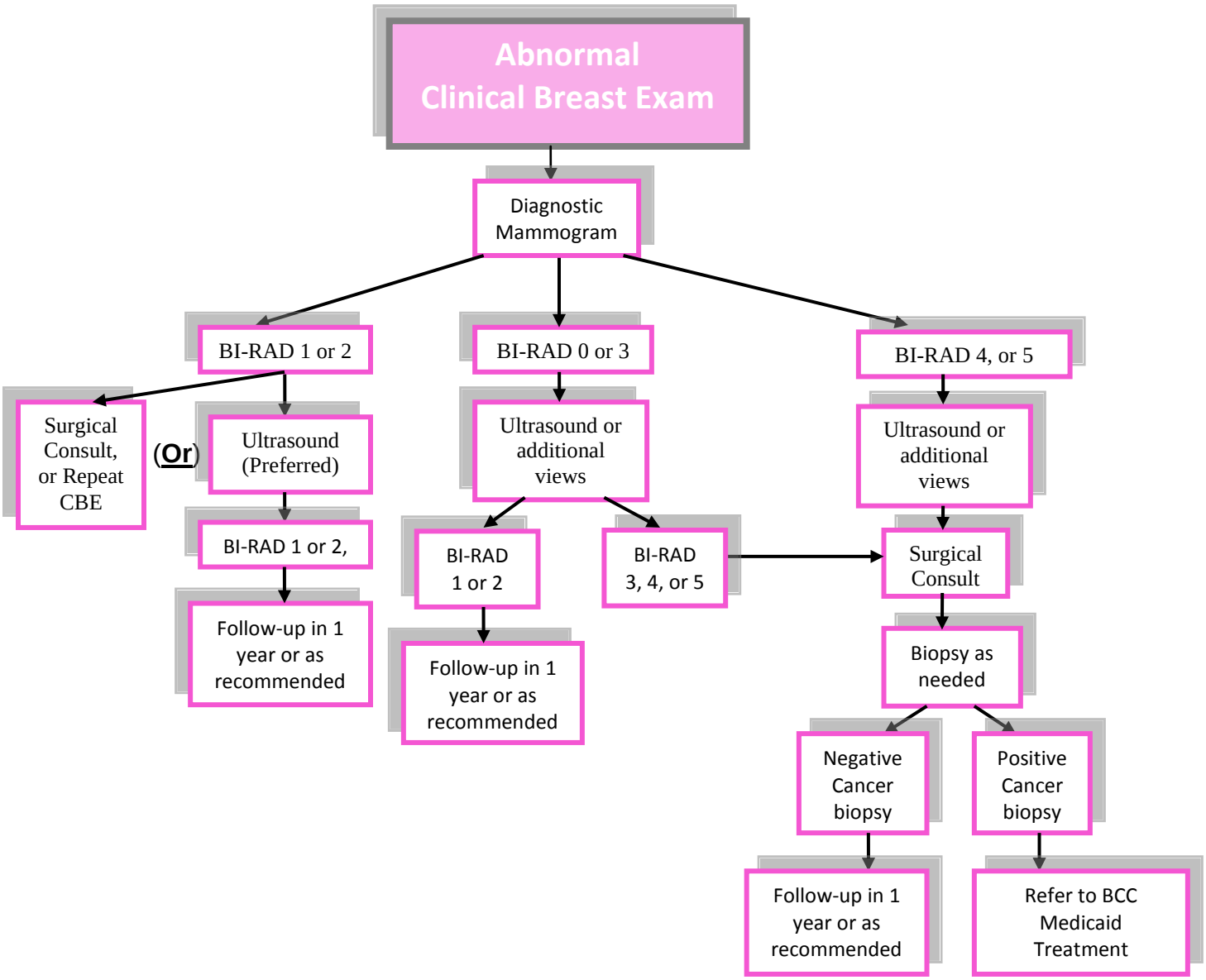
Treatment of breast cancer

If a diagnosis of cancer is made, the provider will need to refer the Breast and Cervical Cancer Medicaid Liaison to start the AL Breast and Cervical Cancer Medicaid treatment

application process. The **ABCCEDP cannot and will not pay for any treatment related services**. This policy is stated in the CDC guidelines.

Note: See breast screening algorithms (page 21 and 22)




Abnormal Clinical Breast Exam
Diagnostic Mammogram
BI-RAD 1 or 2
BI-RAD 0 or 3
BI-RAD 4, or 5
Surgical Consult, or Repeat CBE
(Or)
Ultrasound (Preferred)
Ultrasound or additional views
Ultrasound or additional views
BI-RAD 1 or 2,
BI-RAD 1 or 2
BI-RAD 3, 4, or 5
Surgical Consult
Follow-up in 1 year or as recommended
Follow-up in 1 year or as recommended
Biopsy as needed
Negative Cancer biopsy
Positive Cancer biopsy
Follow-up in 1 year or as recommended
Refer to BCC Medicaid Treatment

Section 7: Cervical Cancer Screening and Diagnostic Services

Cervical Cancer Screening Visit

- ABCCEDP will reimburse for up to two colposcopies per year if warranted based on the abnormal Pap smear or HPV results
- ABCCEDP will not reimburse for routine/annual pelvic exams. Pap smear or Pap smear/HPV must be performed in order for ABCCEDP to reimburse for cervical cancer screening visit

Cervical Cancer Screening Guidelines

- Pap smear frequency for **low risk** patients
  - Conventional Cytology
    - ABCCEDP will reimburse for Pap smear every 3 years for conventional cytology
  - Liquid-based cytology
    - Providers may be reimbursed for liquid based cytology for cervical cancer screening up to the allowable Medicare rate
    - The screening interval when using liquid based tests is:
      - Pap smear every 3 years, or
      - Co-testing with Pap smear and HPV every 5 years

- Pap smear frequency for **high risk** patients
  - ABCCEDP will reimburse for **annual** Pap smears in patients with the following documented risk factors:
    - Infection with Human Immunodeficiency virus (HIV)
    - Immuno-suppressed (such as those with renal transplants)
    - Diethylstilbestrol (DES) exposure in utero
    - Personal history of cervical cancer

- Patients previously treated for CIN ll or CIN lll who have a cervix present -
  - ABCCEDP will reimburse for a co-test at 12 and 24 months. If all results are negative, go to age based screening every 3 years. Patient will need to continue cervical cancer screening for 20 years after the initial post-treatment surveillance period

- Patients who have had hysterectomy
  - ABCCEDP will reimburse for the following in women who have had a hysterectomy:
    - If the cervix is present, follow regimen above for routine smears
    - If the cervix is not present following hysterectomy for CIN ll, CIN lll, or invasive cervical cancer, perform a Pap smear alone (No HPV test) of the vaginal cuff. Continue annual screening for 20 years after the initial post-treatment surveillance period
    - In the event the woman does not know if she has a cervix following hysterectomy for benign reasons, one initial exam can be reimbursed to determine if a cervix is present. If a cervix is not present, a Pap smear will not be reimbursed.

- Abnormal screening results
  - ABCCEDP will reimburse for diagnostic follow-up of women with abnormal screening results (see diagnostic services guidelines)
    - ASCCP guidelines should be followed to determine appropriate diagnostic follow-up
    - Once a woman has completed recommended follow-up, she should again receive Pap tests following the above schedule

- Additional Cervical Screening Guidelines
  - Repeat Pap smear **must not** be within 90 days of previous Pap to be paid
  - No more than 4 repeat Pap smears will be paid in a 12 month period
  - A repeat Pap test will be covered when specimen adequacy is deemed unsatisfactory
  - No reimbursement will be made for a **verifying** Pap smear
  - The presence of endometrial cells in a Pap for a woman over 40 does not necessarily equate to a high risk indicator. As a general rule, further testing when endometrial cells are present in a negative Pap smear will not be covered however, case by case consideration is acceptable for possible exceptions
  - "Endometrial cells" and "specimen lost before evaluation" are the only Pap smear results that should be marked as "other" on the screening form
  - Hyperkeratosis, cervicitis, bacteria and vaginosis are considered to be negative Pap smears
  - Atrophic atypia and atypia should be considered as ASC-US

Adequacy of follow-up for women with abnormal cervical screening results

- A woman whose cervical cancer screening was abnormal or suspicious must receive appropriate diagnostic procedures to arrive at a final diagnosis, and
- Women in whom cervical cancer or CIN ll or lll has been diagnosed must be referred for appropriate treatment

Timeliness of follow-up for women with abnormal cervical cancer screening results

- The interval between initial screening and diagnosis of abnormal cervical screenings should be 60 days or less
- The interval between diagnosis and initiation of treatment for cervical cancer should be 60 days or less

Cervical Screening and Diagnostic Results

Cervical Cancer Screening Results

Normal Results (Pap smear or Pap Smear/HPV)
When the Pap smear or Pap smear with HPV result is normal it is the provider's responsibility to:

- Have a reminder system in place which allows the screening provider to notify the woman prior to the date for routine re-screen (3 year Pap only, 5 year co-test)

Abnormal Screening Result (Pap smear or Pap Smear/HPV)
It is the responsibility of the screening provider to:

- Maintain a record of women receiving Pap smear or Pap smear/HPV to ensure that a report of results is received within two to three weeks of the screening test
- Notify the woman of results and establish a system for tracking these women for appropriate timely follow-up for diagnostic services
- Maintain as a part of the woman's permanent medical record documentation of all test results, related education, resulting recommendations and/or referrals with dates
- Refer women with abnormal screening results for appropriate diagnostic follow-up using ASCCP guidelines
- Plan a diagnostic work-up so that the time from an abnormal Pap smear and/or HPV to final diagnosis should be no more than 60 days

Reimbursement of HPV DNA Testing
HPV DNA is reimbursable for:

- Co-testing with Pap smear every 5 years, OR
- Follow-up to HPV positive result on routine screening
- Follow-up of an ASC-US Pap result, when co-test not done initially

Guidelines for the Management of Abnormal Cervical Cytology

ASC-US:

Terminology	Required Management
ASC-US with HPV Positive	Refer for Colposcopy with biopsy
ASC-US with HPV negative	Co-test every 3 years

ASC-H:

Terminology	Required Management
Atypical Squamous Cells, cannot exclude a high grade squamous intraepithelial lesion	Refer for Colposcopy with biopsy

LSIL:

Terminology	Required Management
Low Grade Squamous Intraepithelial Lesion: Mild Dysplasia (CIN 1)	Refer for Colposcopy with biopsy

Pap/HPV:

Terminology	Required Management
Negative Pap with HPV Positive	Co-test in 1 year

Guidelines for the Management of Abnormal Cervical Cytology: Epithelial Cell Abnormalities

HSIL/CIN 2-3

Terminology	Required Management
High grade Squamous intraepithelial lesion: moderate dysplasia/severe dysplasia/carcinoma-in-situ (CIN 2-3)	Refer for Colposcopy with biopsy
Suspicious for Squamous Cell Carcinoma	Refer for Colposcopy with biopsy
Positive for Squamous Cell Carcinoma	Refer for Colposcopy with biopsy
Atypical Endocervical Cells	Refer for Colposcopy with biopsy
Atypical Glandular Cells	Refer for Colposcopy with biopsy
Atypical Endocervical Cells, favor neoplastic	Refer for Colposcopy with biopsy
Endocervical Adenocarcinoma in site	Refer for Colposcopy with biopsy
Endometrial cells present in menopausal woman; these cells may be associated with an endometrial lesion	Refer for Colposcopy with biopsy or further management
Atypical Endometrial Cells	Refer for Colposcopy with biopsy
Atypical Glandular Cells, favor neoplastic	Refer for Colposcopy with biopsy
Suspicious for adenocarcinoma; origin undetermined	Refer for Colposcopy with biopsy
Adenocarcinoma; origin undetermined	Refer for Colposcopy with biopsy
Adenocarcinoma, most likely of endocervical origin	Refer for Colposcopy with biopsy
Adenocarcinoma, most likely of endometrial origin	Refer for Colposcopy with biopsy
Malignant cells present, site of origin undetermined	Refer for Colposcopy with biopsy

Cervical Diagnostic Services

GYN Consult

- A referral may be made to a GYN for an abnormal Pap smear, only when appropriate and according to the Pap smear follow-up guidelines.
- ABCCEDP will only reimburse GYN consults made for abnormal findings related to cervical cancer.

Abnormal Diagnostic Results (Colposcopy and/or biopsy)

It is the responsibility of the screening/diagnostic provider to:

- Notify the woman of the diagnostic results within 2 – 3 weeks, and establish a system for tracking these women for appropriate timely follow-up and treatment as needed
- Maintain as a part of the woman's permanent medical record documentation of all test results, related education, resulting recommendations and/or referrals with dates
- A colposcopy may be reimbursed if the abnormal Pap smear meets the ABCCEDP follow-up recommendations which are based on ASCCP guidelines
- Reporting requirements for the colposcopy includes the follow-up form, a copy of the Pap smear with abnormal results which initiated the diagnostic procedure, and a copy of the colposcopy examination report
- A second colposcopy can be paid for within a year, if a second Pap smear/HPV indicates a colposcopy is needed. This second Pap smear can be a follow-up Pap smear from the first colposcopy. No more than 2 colposcopies will be paid per woman in a 12 month period and must be at least 3 months apart
- If other circumstances exist, the provider must call the Regional Coordinator for prior approval of payment for additional procedures
- The program will pay for one consult visit prior to the colposcopy and no more than one follow-up visit after the colposcopy if needed
- Colposcopy done as a part of a LEEP **will not be reimbursed**
- A LEEP may be performed for diagnostic purposes only when there are discrepancies between the Pap smear result and the colposcopy biopsy result
- The ABCCEDP will reimburse for up to 2 cervical and 1 ECC biopsies, or 3 cervical biopsies collected during a colposcopy. The number of biopsies will be determined by the number of containers identified by the pathology laboratory
- If a diagnosis of cervical cancer or CIN ll/lll is made, the provider will need to refer the patient to the ABCCEDP Medicaid Liaison to start the AL Breast and Cervical Cancer Medicaid treatment application process

Post-Colposcopy Follow-up

The following post-colposcopy follow-up will be reimbursed by ABCCEDP:

- Patients found to have CIN 1 or less on colposcopic evaluation and biopsy
    - Co-test (Pap and HPV testing) in 1 year
        - If results are $\geq$ ASC or HPV+, refer for colposcopic exam
        - If results are negative cytology and negative HPV, return to routine screening (Pap and HPV) every 3 years
- Patients found to have CIN 2/3 on colposcopic evaluation will, in general, be advised to have treatment with LEEP or Cold Knife Cone (CKC).
    - Post treatment - Negative Margins on LEEP/CKC specimen
        - Repeat co-testing at 12 and 24 months

- If both co-tests are negative, return to routine screening every 3 years
- If any test is abnormal, colposcopy with endocervical sampling is recommended.

- Post treatment - Positive margins on the LEEP/CKC specimen
  - Pap smear and endocervical curettage in 4 – 6 months

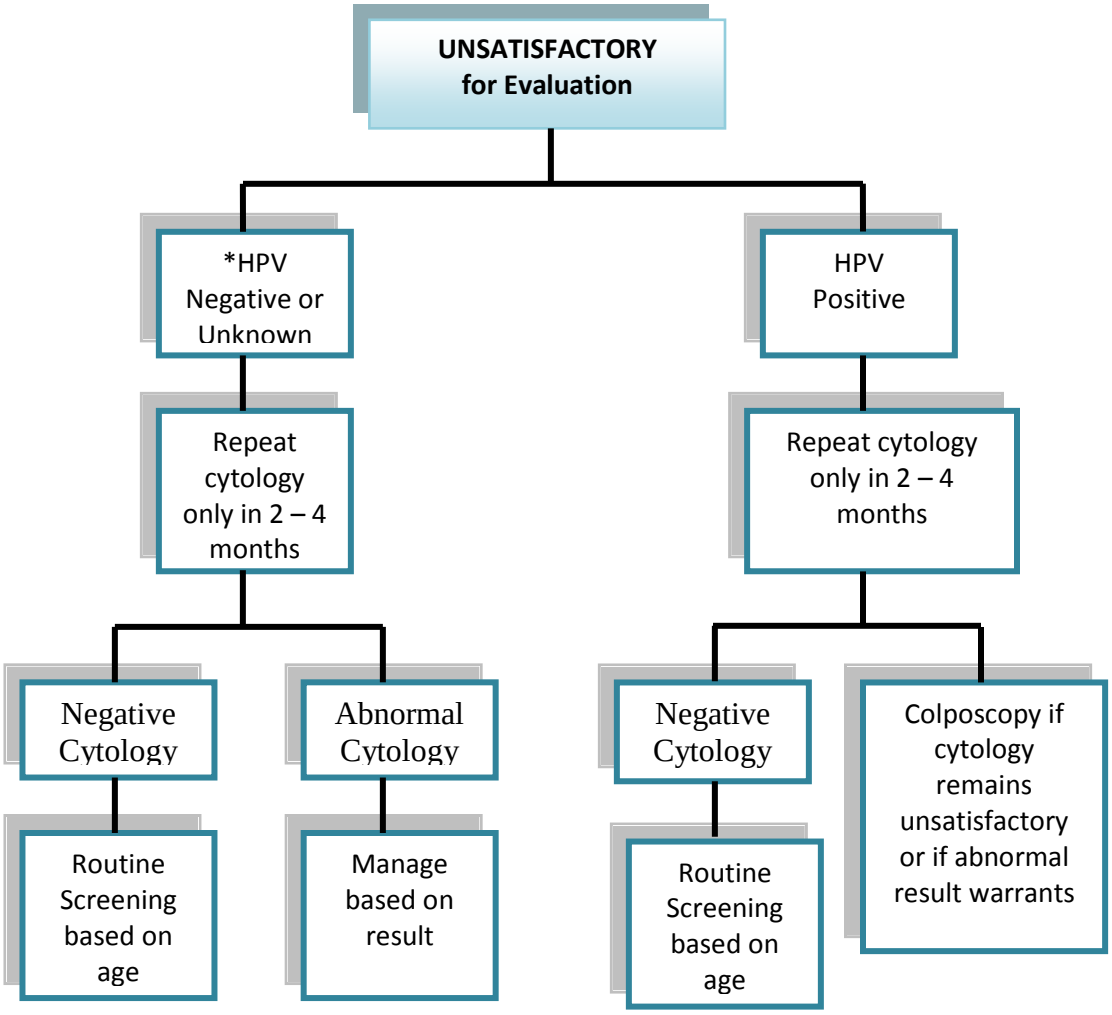
Timeliness of Treatment of cervical cancer or CIN II/III

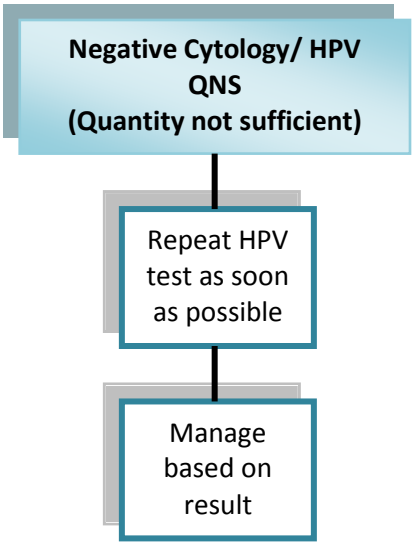
Per CDC guidelines, the **ABCCEDP cannot and will not pay for any treatment related services**. The ABCCEDP provider will need to:

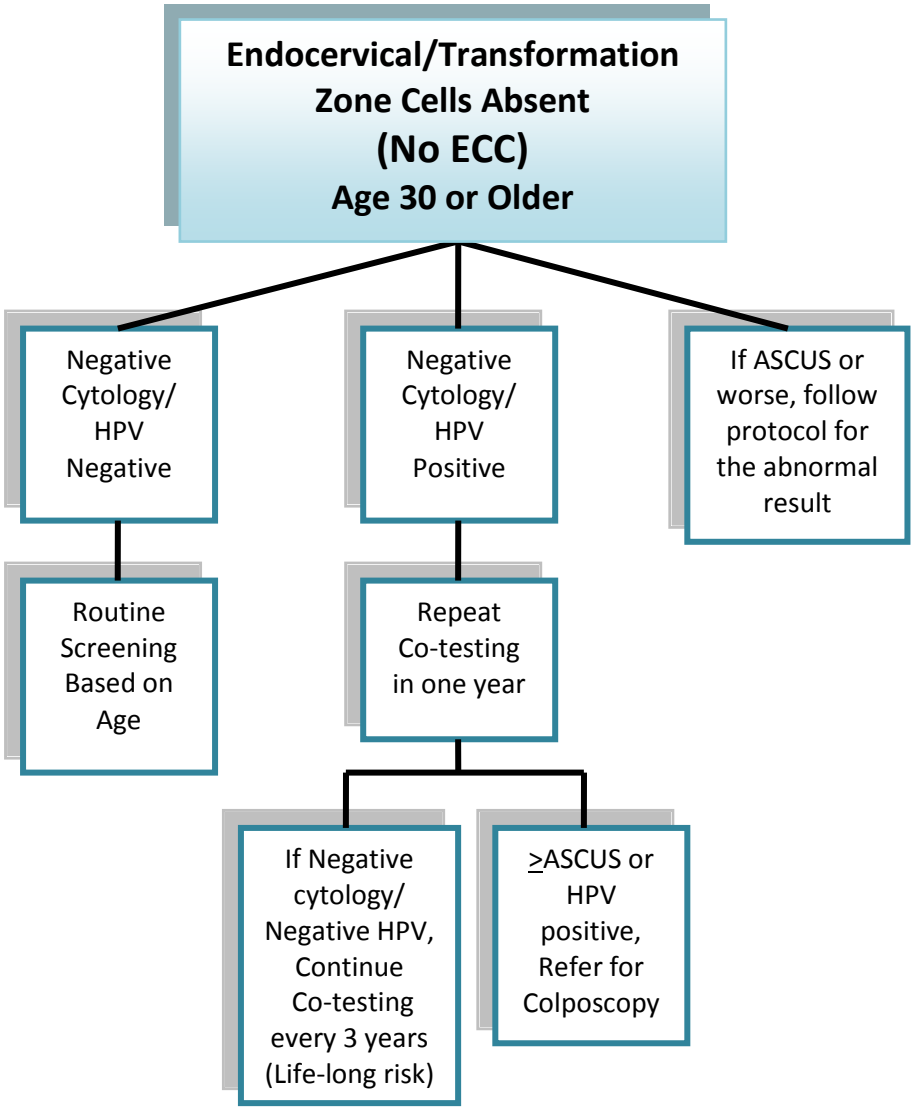
- Refer women with a diagnosis of cervical cancer for treatment so that time from diagnosis to treatment is 60 days or less
- Refer women with a diagnosis of cervical intraepithelial neoplasia (CIN) for treatment so that time from diagnosis to treatment is 90 days or less

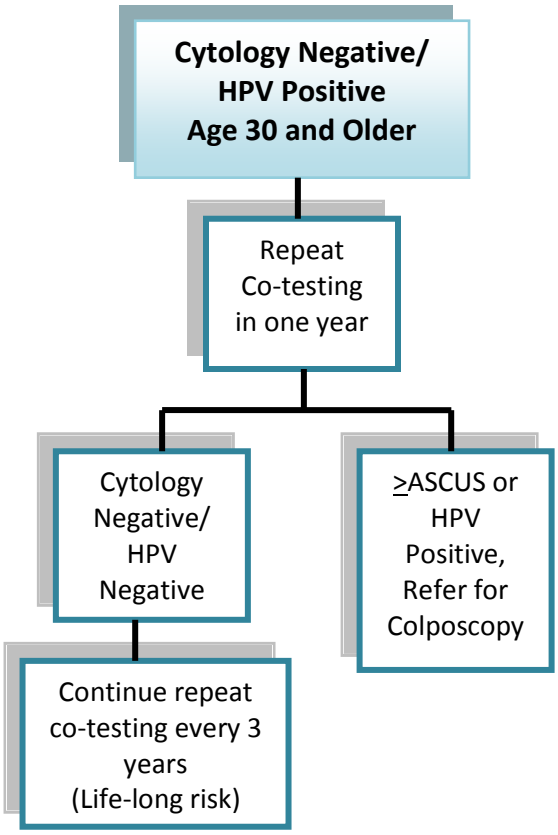
Note: See Cervical Cancer Screening / Abnormal follow-up algorithms (pages 28 – 31)

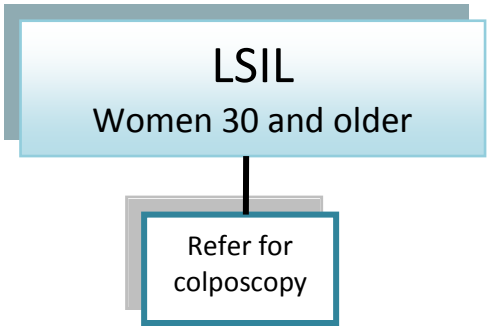
Management of Abnormal Cervical Screening Tests

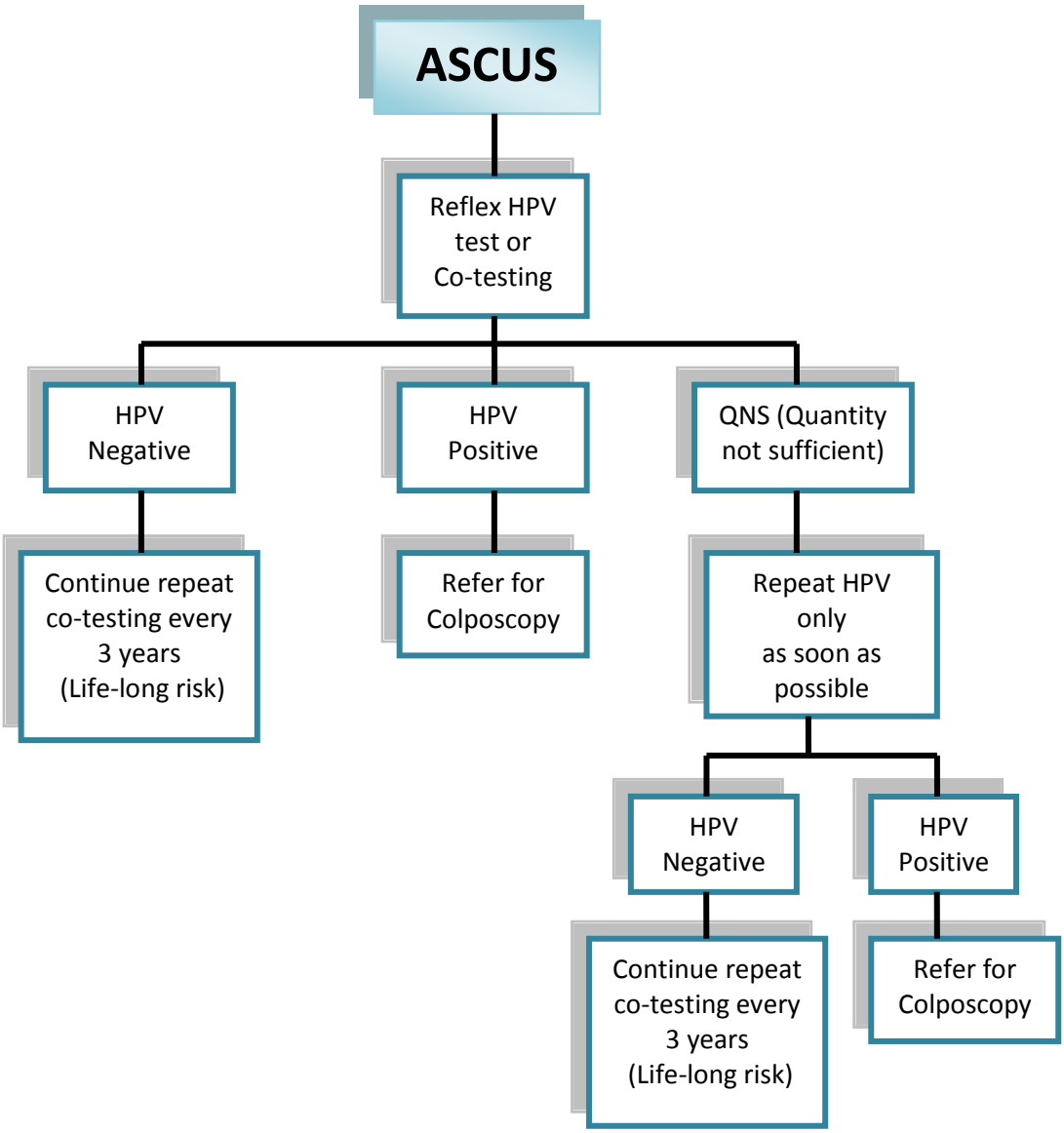



Negative Cytology/ HPV QNS
(Quantity not sufficient)
Repeat HPV test as soon as possible
Manage based on result

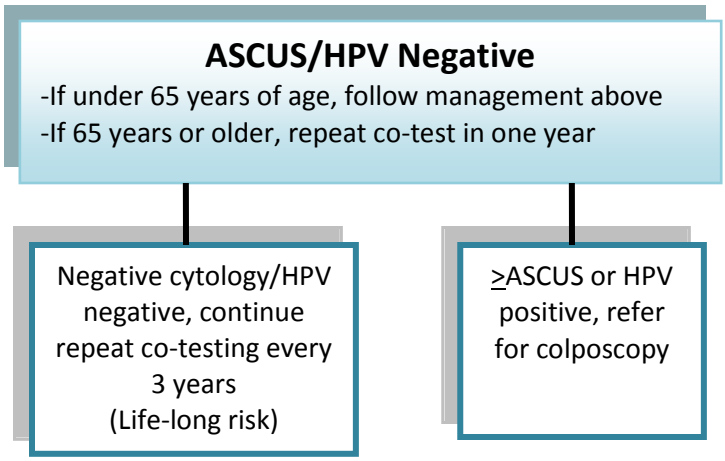

Endocervical/Transformation Zone Cells Absent
(No ECC)
Age 30 or Older
Negative Cytology/ HPV Negative
Negative Cytology/ HPV Positive
If ASCUS or worse, follow protocol for the abnormal result
Routine Screening Based on Age
Repeat Co-testing in one year
If Negative cytology/ Negative HPV, Continue Co-testing every 3 years (Life-long risk)
≥ASCUS or HPV positive, Refer for Colposcopy


Cytology Negative/
HPV Positive
Age 30 and Older
Repeat
Co-testing
in one year
Cytology
Negative/
HPV
Negative
≥ASCUS or
HPV
Positive,
Refer for
Colposcopy
Continue repeat
co-testing every 3
years
(Life-long risk)


LSIL
Women 30 and older
Refer for
colposcopy



ASCUS - Postmenopausal Women



Breast & Cervical CANCER EARLY DETECTION Program of Alabama

PROGRAM FORMS

AND

DATA COLLECTION

Section 8: ABCCEDP Forms and Data Collection

Purpose

The ABCCEDP has **mandatory** reporting requirements for the federal funds received and data elements that are required by the CDC. CDC will use the data from all states receiving screening money and report to Congress that the money is being properly used. The data collected from the ABCCEDP forms provides evidence to the funding agencies (the state legislature and the federal government) that the money they are providing is serving clients who are eligible and in need of the program.

These data elements are collected:

- To ensure the women receive breast and cervical cancer screening tests at appropriate intervals
- To ensure the women are referred for timely follow-up and are provided diagnostic and treatment services, if necessary
- To ensure that the program is reaching the in-need segment of the population
- To collect data on race, ethnic origin, marital status, education, the referral source, and how the woman heard about the program
- To ensure the women are sent reminders of screening times
- To evaluate the effectiveness of the ABCCEDP

Form Completion and Submission for Payment

Original screening form, HCFA and diagnostic/follow-up forms:

- Should be completed and mailed to the Regional Coordinator with an invoice by the **fifteenth of each month** with a copy of results
- All forms can be printed from the ABCCEDP Enrollment web site. The original forms will be sent to the Regional Coordinator
- The original mammography voucher is given to the patient for her to give the mammography facility at the time of her visit
- Copies of all forms must be kept in the woman's file
- The consent must be signed and the original signed document maintained in the patient's medical record

Screening Form and HCFA 1500 or UB 92

The purpose of the screening form and HCFA or UB:

- To provide documentation of the screening and diagnostic work up plan
- To be completed on all women receiving a partial, complete screening or re-screening at the time service is provided
- To serve as the monthly data report on provider activity and the documentation for billing
- Generated by the primary provider at the time of the breast and or cervical screening

The screening form has questions that trigger a Referral/Follow-up if any of the following are marked. A Follow-up form would be generated and a referral made if:

Cervical Screening:	Pap Smear/HPV Results: If any results other than Negative/Benign, patient should be referred per ASCCP guidelines. Cervical Screening Disposition: response of further diagnostics test necessary.
Breast Screening:	CBE Findings: If any results other than Negative/Benign, patient should be referred for further evaluation. Mammogram Results: If any results other than Negative/Benign, patient should be referred for further evaluation. Breast Screening Disposition: response of further diagnostics test necessary.

- Follow-up forms submitted without one of these triggers on the screening form will be questioned and reimbursement for the diagnostic procedures will not be made unless approved
- The results of screening tests should be carefully recorded so that women receive adequate follow-up and providers receive proper payment
- If the result of the breast or cervical screening recommends a repeat exam in the near future, such as 3 to 6 months later, **do not** complete a follow-up form. At the time the woman returns for her repeat exam, a new screening form should be initiated
- The follow-up form is for cases where immediate diagnostic tests/procedures are necessary to determine cancer status

Mammography Voucher

The purpose of the mammography voucher is:

- To show verification of payment by the program to the mammography facility
- To provide any identifying, or pertinent exam information to the mammography facility
- To document that the mammogram has been performed on the correct patient

The mammography voucher **must** be completed by the primary provider and the original sent with the woman to the mammography facility. A copy is kept in the woman's chart. The mammography facility **must** forward this form, a HCFA 1500, with the woman's mammography report to the Regional Coordinator when the facility bills for services.

Breast / Cervical Diagnostic/Follow-Up Form

The Breast or Cervical Diagnostic Follow-up form is utilized when breast or cervical related diagnostic follow-up is required. The purpose of the forms is:

- To provide a mechanism for ABCCEDP women to be referred for further diagnostic testing
- To provide documentation of the tests performed and track information needed for follow-up
- Provide information to the referring physician
- For the woman to take to the referral physician (original to referral physician and a copy for the woman's chart) at the time of the appointment
- For the referral physician to complete the remainder of the form pertinent to the tests that are performed; forward the original form and HCFA to the Regional Coordinator with the bill and documentation of the visit
- The referral physician is also responsible for providing the primary provider with a copy of the tests results, final diagnosis, tumor size, and treatment if necessary.
- The completed follow-up form, HCFA 1500, physician notes (if a GYN or surgeon) along with any biopsy, ultrasound or surgeon reports must be submitted to the Regional Coordinator

How to Change Client Information

If there are changes in client information after you have submitted the screening form or follow-up form for the client, notify the Regional Coordinator in writing of the change to be made. Include in your note the following, so that the correct record is changed:

- Name that is currently in ABCCEDP records
- Social Security Number
- Date of Birth
- Medical Record Number
- CBE or Pap Smear Date
- Changes in patient name

Breast & Cervical CANCER EARLY DETECTION Program of Alabama

Alabama

Breast and Cervical Cancer

Treatment

And

Case Management

Section 9: Referral to the Alabama Medicaid Breast and Cervical Cancer Treatment Program

Purpose

Initiated in October of 2001, the Alabama Medicaid Agency program provides coverage for eligible women diagnosed with breast or cervical cancer to receive treatment for their cancer.

Eligibility

To apply for this program, the woman must:

- Have a breast or cervical cancer diagnosis
- Live in Alabama
- US Citizen or Legal US resident for at least 5 years
- Not have credible insurance that covers cancer treatment
- Be at or below 200% of the Federal Poverty Level
- Complete the required application forms

To remain eligible for this program, the woman must meet following criteria:

- Receiving active cancer treatment which includes at least one of the following:
    - Surgery related to the diagnosis of breast or cervical cancer
    - Chemotherapy
    - Radiation therapy
    - Treatment with long term hormone therapy for breast cancer with medications such as Femara or Tamoxifen
    - Breast Reconstruction (must be done within 2 years of mastectomy)
    - Active treatment must be confirmed by treating physician
- Be under age 65
- Live in Alabama
- Not have become eligible for other insurance that would pay for cancer treatment (ie: Medicare or SSI Medicaid)

The woman is eligible to **re-apply** for this program if:

- She has a recurrence or metastasis of breast or cervical cancer
- She was terminated from the B & C Medicaid because she became eligible for SSI Medicaid benefits and is later terminated from that program and is still in active treatment or on long term hormonal therapy

Cancer Diagnoses that are eligible for treatment must have a positive biopsy pathology result reading for

- Breast Cancer **OR**
- Cervical Cancer/Pre-cervical cancer of either:
    - CIN II/Moderate to Severe Dysplasia
    - CIN III/Severe Dysplasia/CIS
    - Invasive Cervical Cancer

Provider Responsibilities for Referral to the Program

The ABCCEDP provider must mail or fax the following information to the ABCCEDP Medicaid Liaison:

- A copy of the positive pathology biopsy report
- The woman's demographic information
- A statement as to whether the woman knows her diagnosis
- The planned treatment schedule and date

The Application Process

After the ABCCEDP Medicaid Liaison receives the required information from the provider:

- The woman is sent the Medicaid application with instructions to return the original application via US mail. The completed application cannot be faxed
- The application will be forwarded by the Medicaid Liaison to Medicaid for processing
- Retro-active coverage is available for up to 3 months if requested and can be awarded beginning the first day of the month of diagnosis
- The time frame from the time the application is sent to Medicaid and receiving an award date is usually no more than two weeks
- The Medicaid Liaison checks the Medicaid system daily and notifies the patient when Medicaid decision regarding Medicaid eligibility has been made
- Medicaid will notify the woman by letter when she has been approved or denied and if approved her card will be mailed
- The ABCCEDP Medicaid Liaison will notify the woman by phone call once it is determined that her Medicaid has been approved

Covered Services Information

The Breast and Cervical Treatment Program provides full Medicaid benefits including treatment for cancer. Examples of some of these services are:

- Cancer surgery treatment
- Chemotherapy treatment
- Radiation treatment
- Long term therapy (ie: Tamoxifen, Arimidex, Femara, Herceptin, etc.)
- Breast Prosthesis
- Breast Reconstruction (Must get pre-approval from Medicaid and the time frame for doing this is 2 years from the date of surgery)

Medicaid Liaison's Contact Information

The ABCCEDP Medicaid Liaison can be reached at the following numbers:

- Phone number - 334-206-2976
- Fax - 334-206-3738.

Section 10: Case Management

Overview

The goal of case management for the ABCCEDP is to ensure that women enrolled in the program receive timely and appropriate rescreening, diagnostic, and treatment services. The need for case management initiation will be determined at initial enrollment or upon receipt of abnormal screening results or a diagnosis of cancer

Policy

The National Breast and Cervical Cancer Early Detection Program (NBCCEDP) policy states that "women with an abnormal screening result or with a diagnosis of cancer are the priority population to receive case management services"

Abnormal screening results are listed below:

- **Clinical breast exam** which is suspicious for cancer. This includes discrete palpable mass, bloody or serous nipple discharge, nipple or areolar scaliness, and skin dimpling or retraction
- **Mammogram** with BIRAD results of BIRAD 0 (assessment is incomplete and additional imaging is needed), BIRAD 4 (suspicious abnormality, biopsy should be considered), or BIRAD 5 (highly suggestive of malignancy, appropriate action should be taken)
- **Pap Smear** with abnormal results showing HSIL, AGUS, squamous cell carcinoma, and adenocarcinoma

Individual Patient Case Management Process

The following circumstances would initiate ABCCEDP case management services:

- A provider requests that a specific woman receive case management services
    - If at any time the provider is doing in-house case management and needs assistance, the ABCCEDP Regional Coordinator should be contacted for help. The Regional Coordinator will contact the Case Management Coordinator if needed. Providers will be encouraged to refer problem patients as soon as possible

- A woman requests case management
    - Providers will be responsible for informing women of the availability of case management services when they are enrolled or when abnormal results are received. The informed consent will address case management and the possibility of referral if abnormal screening results occur. The woman may at any time self refer if the provider does not initiate the process

- A woman is identified as needing case management by the ABCCEDP staff
    - The Regional Coordinator will contact the Primary Care Provider (PCP) if there is evidence there is a woman with an abnormal result without completed follow-up. Monthly overdue reports, information from the screening form, and monthly

review of the minimum data elements (MDEs) will alert the Regional Coordinator of potential patients

Referral for Treatment **- A definitive diagnosis of cancer** would also require immediate assessment, and in addition, require notification of the ABCCEDP Medicaid Liaison**.** Case management services conclude when a client initiates treatment, or is no longer eligible for services. A client may return to a schedule of routine screening in the ABCCEDP and receive all its services following her completion of treatment.

Because of the number of individuals that may be involved in the case management process it is imperative that the professionals involved remain in communication with each other. That would involve the faxing, mailing, or phoning of all information and documentation that is available. All efforts and activities of the case management process must be DOCUMENTED and placed in the woman's chart.

Breast & Cervical CANCER EARLY DETECTION Program of Alabama

GLOSSARY

ADPH	Alabama Department of Public Health
ABCCEDP	Alabama Breast and Cervical Cancer Early Detection Program
BSE or SBE	Breast Self Examination
Central Office Staff	ABCCEDP staff at the State level
CBE	Clinical Breast Examination
CDC	Centers for Disease Control and Prevention
Contract	Legal binding agreement to ABCCEDP enrollees for payment of services rendered between the ADPH and Provider
Enrollee	An eligible woman enrolled in the ABCCED Program
Provider	Refers to a physician, hospital, rural health clinic, ADPH clinic, or laboratory that has agreed to participate in the ABCCEDP, and provide service to women who meet the eligibility requirements
NBCCEDP	National Breast and Cervical Cancer Early Detection Program
Regional Coordinator	The Regional Coordinator is responsible for the coordination of screening services in designated counties.
Screening Cycle	Cycles begin with a CBE, pelvic examination, Pap smear, referral for mammography and typically conclude with a normal screening result. For a woman with an abnormal screening result, the screening cycle may not be completed until diagnostic work-up, final diagnosis, and treatment data are complete
Screening Provider or Provider	Refers to the health department and primary care facilities, or private primary providers under contract with the Alabama Department of Public Health to provide screening services
Screening Services	Screening services refers to clinical breast exam, Pap smear, pelvic exam, instruction in breast self examination, referral for screening mammogram (if age appropriate) and information and educational services relating to breast and cervical cancer.