BREAST AND CERVICAL CANCER
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BREAST AND CERVICAL CANCER

The ADPH Cancer Detection Program provides a means for screening women for breast and cervical cancer. This program is primarily funded through the Alabama Breast and Cervical Cancer Early Detection Program (ABCCEDP) and follows the guidelines established by that program.

ABCCEDP Overview:

The Alabama Breast and Cervical Cancer Early Detection Program (ABCCEDP) was established by Title XV of the Public Health Services Act, known as the "Breast and Cervical Cancer Mortality Prevention Act of 1990" (Public Law 101-354). This program is funded through the Centers for Disease Control and Prevention (CDC) for the detection and control of breast and cervical cancer.

The purpose of the ABCCEDP is to prevent unnecessary disease, disability, and premature death due to cancer of the breast or cervix by providing early detection, screening and referral services.

Clinical Guidelines:

The ABCCEDP clinical guidelines are based on CDC grant requirements and recommendations with input from the ABCCEDP Medical Advisory Committee.

Patient Enrollment:

All women must be enrolled in the ABCCEDP prior to receiving a screening. This enrollment will be done by Health Department staff through a web-based program. 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.

Resource Documents:

NBCCEDP Program Guidance Manual – Revised 10/2012

CHR Manual: See CHR-3 for Consent Form regarding provision of patient services.

Consensus Guidelines for Managing Abnormal and Cervical Pathology (ASCCP); 2012 Updated Consensus Guidelines for Managing Abnormal Cervical Cancer Screening Tests and Cancer Precursors; Algorithms, reprinted April 2013.

Evaluation of Common Breast Problems: Guidance For Primary Care Providers, CA CANCER J CLIN 1998: 48: 49-63.

ELIGIBILITY GUIDELINES

To be eligible for the ABCCEDP, a woman must meet the following age, income and insurance criteria:

- **Age**: See document library for current age and available services eligibility
- **Income:** Must be at or below 200% of the Federal Poverty Income Guidelines. Patient declaration is acceptable. Verification is not required.
- **Insurance:**
  - Client is uninsured
  - Client is underinsured
    - Has health insurance but cannot afford existing co-pay or deductible; or has health insurance that does not fully cover screening services.

Treatment – ABCCEDP cannot provide reimbursement for any treatment related services. However, clients who are diagnosed with breast, cervical, or pre-cervical (CIN ll or lll) cancer **may** be eligible to apply for the AL Medicaid Breast and Cervical Cancer Treatment Program. Contact your ABCCEDP Regional Coordinator regarding any client diagnosed with breast or cervical cancer.

NOTE: Tracking Numbers
When enrolling patients in ABCCEDP a tracking number will be assigned

Website: http://adph.org/early detection/
- Go to: Patient enrollment
  - ABCCEDP Online Med-it System

For problems with password, please contact your Regional Coordinator.

Cancer Screening Guidelines and Management - Breast

A. Guidelines for Breast Screening:
   - See document library for current age eligibility and available services eligibility

B. The American Cancer Society guidelines for screening mammography are outlined below. For those mammograms reimbursed by ABCCEDP, *Komen Foundation*, Joy *to Life Foundation*, or *National Breast Cancer Foundation* refer patient to ABCCEDP contracted providers only.

C. The American Cancer Society recommends a three-part breast health program. For asymptomatic women this includes monthly breast self examination (BSE), annual clinical breast exam (CBE), and annual screening mammography after age 40.

D. Breast Abnormality suspicious for cancer:

   See **Abnormal Findings Chapter, "Breast Abnormalities"** later in this manual

E. Definitions:
   - Screening Mammogram – This is a radiologic exam to detect unsuspected breast cancer at an early stage in asymptomatic women.
   - Diagnostic Mammogram – This is a radiologic exam to evaluate a patient with a breast mass, other signs or symptoms, or an abnormal or questionable screening mammogram.
   - Breast Abnormality – A thickening or lump felt in a woman's breast which may or may not have the following characteristics: nipple retraction, dimpling, inflammation, palpable axillary or supraclavicular nodes, tenderness, discharge from nipple.
   - Breast Ultrasound – This is an ultrasonic exam to evaluate a breast mass based on an abnormal CBE; or as follow-up to a mammogram
   - BI-RAD – Breast Imaging-Reporting and Data System. Standardized numerical codes assigned by a radiologist after interpreting a mammogram.
     - BI-RAD 0 – Radiologic assessment incomplete – need additional imaging
     - BI-RAD 1 – Negative
     - BI-RAD 2 – Benign Finding
     - BI-RAD 3 – Probably Benign – short term follow-up 3 – 6 months
     - BI-RAD 4 – Suspicious Abnormality
     - BI-RAD 5 – Suggestive of Malignancy

Reimbursement Reminders

- Annual visits – The ABCCEDP pays for one comprehensive visit each 12 month period (visits must be greater than 10 months apart).

- Follow-up visits – ABCCEDP will reimburse 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

- Screening Mammogram – Only one screening mammogram will be paid during a 12 month period. Referrals for routine screening mammograms should be 1 year apart, but in no case less than 10 months. CBE must have been performed in the last 6 months

- Diagnostic Mammogram – No more than three (3) mammograms per woman will be reimbursed in a 12 month period.

- Breast MRI (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 age 40 – 64 who meet 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.

- Surgeon Referral/Consultation visits – For a surgeon referral to be reimbursed, one of the following requirements must be fulfilled:
    a. 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
    b. An abnormal mammogram with result of BI-RAD 4 or 5
    c. An abnormal ultrasound suspicious for cancer

- Ultrasound – An ultrasound will be reimbursed when clinically indicated

- Abnormal CBE with normal diagnostic mammogram – A diagnostic mammogram alone is not adequate follow-up for an abnormal CBE. CDC requires that the patient also has one of the following:
  - Ultrasound
    and/or
  - Surgical Consult

- Ductograms - Ductogram is a reimbursable service when the patient meets the following criteria:
  - 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

Non Reimbursable Services

- Breast Cytology – ABCCEDP will not reimburse for cytology testing of a breast discharge.
- Breast Implants – ABCCEDP will not pay for any procedures related to breast implants other than those related to a breast cancer diagnosis.
- Counseling/referral only visit – CBE (Pap smear) must be indicated and performed.
- Gamma imaging – ABCCEDP will not reimburse for these procedures.

Cancer Screening Guidelines and Management - Cervical

A. Guidelines for Cervical Screening:
   - See document library for eligibility regarding age and current services available

B. Routine Pap Smears
   1. Low Risk patients – Pap smear and HPV every 5 years

   2. High Risk patients - Patients with the following documented risk factors will continue to receive **annual** Pap smears:
      - Infection with Human Immunodeficiency virus (HIV)
      - Immuno-suppressed (such as those with renal transplants)
      - Diethylstilbestrol (DES) exposure in utero
      - Diagnosed with cervical cancer

      Patients Previously treated for CIN ll or CIN lll –
      - 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 screening for 20 years after the initial post-treatment surveillance period.

C. Hysterectomy
   1. If the cervix is present, follow regimen above for routine smears.
   2. If the cervix is not present, perform a Pap smear (vaginal cuff) **only** if: hysterectomy was done due to pre (CIN ll or lll) or Cervical Cancer
   3. In the event that the woman does not know if she has a cervix following the hysterectomy, 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.

D. Cervical Abnormality suspicious for cancer;
   See **Follow-up Chapter "Pap smear Protocol" for clinical management.** This chapter is located later in this manual

E. Definitions:
   - Pap Smear - A procedure in which cells are scraped from the cervix for examination under a microscope. It is used to detect cancer and changes that may lead to cancer.
   - Colposcopy – Examination of the vagina and cervix using a lighted magnifying instrument called a colposcope.

Cancer Screening Guidelines and Management- Cervical

Reimbursement Reminders

- Annual visits – The ABCCEDP pays for one comprehensive visit each 12 month period (visits must be greater than 10 months apart).

- Pap Smear – ABCCEDP will pay for the following:
  - Pap smear and HPV every 5 years
  - No more than 3 repeat Pap visits will be paid during a 12 month period.
  - Repeat Pap smears need to be at least 90 days apart.

- Colposcopy – ABCCEDP pays for up to two colposcopies per year if warranted based on the abnormal Pap smear or HPV results.

Non Reimbursable Services

- Pelvic Ultrasound

- A counseling/referral only visit – A Pap smear must be indicated and performed.

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ABCCEDP VISIT STANDARDS - INITIAL/ANNUAL

The purpose of this visit is to provide cancer screening services to a patient enrolled in the ABCCEDP. This visit captures screening visits for new or established ABCCEDP patients.

- Initial Visit: Code as "CD Initial-01" on the ADPH Clinical Services Encounter Form.
- Annual Visit: Coded as "CD Annual-05" on the ADPH Clinical Services Encounter Form.

CHR- 2 Determine and document eligibility based on age, insurance, and income status.

CHR- 3 Make sure consent for services is reviewed and signed

CHR -11 Check Blood Pressure

CHR- 12A - Side 1

Provide Counseling to Address:

1. Patient concerns
2. Provider identified patient counseling needs (based on assessment)
   a. Instruction on technique and reinforcement of the importance of monthly BSE; annual CBE, biennial Pap smear, and annual mammogram age 40 and older.
   b. Counsel patient that it is out of the scope of ADPH to manage existing or suspected medical problems unrelated to breast and cervical screening (such as hypertension, diabetes, etc.) Referral would be indicated to address these medical needs.
   c. Counsel patient of importance of follow up if abnormal screening results are reported and that the ABCCEDP will pay for indicated referral and diagnostic testing based upon suspicion for breast and cervical cancer.

CHR-12A - Side 2

Perform a Physical Exam:

General appearance; breast (CBE); genito-urinary (it is ADPH policy that all patients should receive a pelvic exam consisting of speculum exam and bimanual exam, regardless of history of hysterectomy); and rectal exam. A complete physical exam is not required but may be performed.

Perform Pap Smear - see Screening Guidelines, previous page.

Referral:

Breast: see Abnormal Findings Chapter, "Breast Abnormalities", later this manual

- **Surgeon Referral/Consult** – For a surgeon referral to be reimbursed, one of the following requirements must be fulfilled:
  a. An abnormal CBE, suspicious of cancer (to include palpable mass, bloody or serous discharge, nipple or areolar scaliness or retraction, or skin dimpling), regardless of mammographic findings.
  b. An abnormal mammogram with result of BI-RAD 4 or 5.
  c. An abnormal ultrasound suspicious for cancer.

ABCCEDP VISIT STANDARDS - INITIAL/ANNUAL

(Continued)

Breast:

a. Refer for screening mammography based on American Cancer Society guidelines. For those mammograms reimbursed by ABCCEDP, *Komen Foundation, Joy to Life Foundation*, or *National Breast Cancer Foundation* refer patient to ABCCEDP contracted providers only.

Cervical: See Follow-up Chapter, Pap Smear protocol, later in this manual

- Gross cervical lesion suspicious for cancer noted upon exam
- Abnormal Pap result

ABCCEDP Forms:

Complete and Submit the Following Form(s) to the ABCEDP Regional Coordinator: Refer to the ABCCEDP Provider Manual for detailed instructions if needed. Forms are on the ABCCEDP Enrollment System website.

- **Mammography Voucher** - complete if indicated; give original to patient after making mammogram appointment; keep copy in chart and follow-up/tickler file.
- **Screening/Billing form** - complete form at each patient visit; submit original to the ABCCEDP Regional Coordinator; keep copy in chart.
- **Breast Diagnostic Follow Up** form **and/or ABCCEDP Cervical Diagnostic Follow Up** form – complete if indicated; give original to patient after making the appointment; keep copy in record; send copy with S/B Form to ABCCEDP Regional Coordinator.
- **HCFA 1500 Billing Form** – Complete the form after results of lab work have returned (Pap smear, HPV). Send original to ABCCEDP Regional Coordinator.

Note: For ABCCEDP reimbursement, referral for diagnostic services must be made to ABCCEDP contracted physicians and facilities only.

CLINICAL INDICATORS:

1. Case Management - Case Management (CM) services may be initiated by the patient if requested, or by the provider if indicated to assist the patient with accessing care for screening or diagnostic services. The CM process may also be initiated by the ABCCEDP Regional Coordinator following abnormal high risk results such as a CBE suspicious for cancer; mammography results of a BI-RAD Category 0, 4 or 5; or Pap results of ASC-H or worse. The ABCCEDP Regional Coordinator should be contacted to initiate CM services.
2. Utilize STD protocol for STD related problems.
3. Refer to the Abnormal Findings Chapter, Abnormal Uterine Bleeding, if applicable.
4. Refer to Abnormal Findings Chapter “Urinary Tract Infection-UTI,” for urinary complaints and prescription from NP if indicated

CLINICAL INDICATORS CONTINUED:

5. Colorectal screening/Fecal Immunochemical testing (FIT Test): **Not reimbursable by ABCCEDP**
   - Routine Annual Screening:
     - **a.** Women age 50 years of age and older
     - **b.** African American women beginning at age 45

   - Colonoscopy referral is recommended for patients with the following risk factors for colorectal cancer:
     - **a.** A strong family history of colorectal cancer or polyps (cancer or polyps in a first degree relative (parent, sibling, or child) younger than 60 years of age, or in 2 first degree relatives of any age)
     - **b.** A known family history of hereditary colorectal cancer syndromes such as familial adenomatous polyposis (FAP) or hereditary non-polyposis colon cancer (HNPCC)
     - **c.** A personal history of colorectal cancer of adenomatous polyps
     - **d.** A personal history of inflammatory bowel disease Crohn's disease or ulcerative colitis)

       ❖ Note: Only in a case where the high risk patient refuses referral for colonoscopy will ADPH offer the FIT test with counseling and documentation that colonoscopy is the standard of care.

     Reference: ACOG; Committee Opinion, Number 482, Colonoscopy and Colorectal Cancer Screening Strategies, March 2011; American College of Gastroenterology Guidelines for Colorectal Cancer Screening 2008; Am J Gastroenterol 2009; 104:739-750; doi: 10.1038/aja.2009.104 published online 24 February 2009; and the American Cancer Society.

   - Refer patients with positive FIT results to provider for evaluation

ABCCEDP VISIT STANDARDS – REVISIT

This is a problem-focused visit for the following patients:

An established ABCCEDP patient - This visit may be indicated for reasons such as: follow-up assessment of an abnormal finding from a previous visit; assessment of a new breast complaint or for performing a repeat Pap smear (generally post-colposcopy). Utilize the "Cancer Detection (CD) Revisit" - code as "CD Revisit – 02" on the ADPH Clinical Services Encounter Form.

CHR - 2 Update and document eligibility based on age, insurance, and income status.
CHR - 3 Make sure consent for services is reviewed and signed
CHR - 11 Check Blood Pressure
CHR -10 or CHR-12A ▪ Document purpose of visit. ▪ Provide problem-focused assessment. ▪ Provide problem-focused counseling. (Note: ABCCEDP reimbursement is based on eligibility guidelines) ▪ Perform/Refer – if indicated per ABCCEDP guidelines 1. Repeat Pap smear 2. CBE 3. Diagnostic mammography 4. Breast Ultrasound 5. Surgeon referral/consultation Note: For ABCCEDP reimbursement, referral for diagnostic services may be made to ABCCEDP contracted physicians and facilities only.

ABCCEDP Forms:
Complete and Submit the Following Form(s) to the Regional Coordinator: Refer to the ABCCEDP Provider Manual on the ABCCEDP website at http://adph.org/early detection/ for detailed instructions if needed. Other ABCCEDP Forms are also available on this website.

- **Mammography Voucher** - complete if indicated; give original to patient after making mammogram appointment; keep copy in chart and follow-up/tickler file.
- **Screening/Billing form** - complete form at each patient visit; submit original to Regional Coordinator; keep copy in chart.
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2. Utilize STD protocol for STD related problems.
3. Refer to the Abnormal Findings Chapter, Abnormal Uterine Bleeding, if applicable
4. Refer to Abnormal Findings Chapter “Urinary Tract Infection – UTI,” for urinary complaints and prescription from NP if indicated.

OTHER PROTOCOL

The following are additional program guidelines. See ABCCEDP Provider Manual on the ABCCEDP website at http://adph.org/early detection/ for additional information.

CHARGING FEES

- ABCCEDP Reimbursable services are free to eligible patients. The patient cannot be charged any fees for Reimbursable program services at any time.
- The patient needs to be informed that ABCCEDP Non-Reimbursable services will not be covered.

TREATMENT

ABCCEDP **cannot** provide reimbursement for any treatment related services. Clients who are diagnosed with breast, cervical, or pre-cervical (CIN ll or lll) cancer **may** be eligible to apply for the AL Medicaid Breast and Cervical Cancer Treatment Program. Contact your ABCCEDP Regional Coordinator regarding any client diagnosed with breast or cervical cancer.

FOLLOW-UP/TRACKING PROTOCOL

The ABCCEDP uses the follow-up and tracking protocol outlined in the Abnormal Findings and Follow-up Chapters later in this manual. This policy includes management for mammography results as well as Pap smear protocol. The Pap smear protocol describes the Bethesda reporting system, Pap smear nomenclature, management of abnormal results and follow-up requirements.

QUALITY ASSURANCE

The ABCCEDP Regional Coordinators will complete annual performance review visits during the first six months of every year. The results of the Quality Indicator Report will be shared with the Health Department staff. If all Quality indicators are satisfactory, a visit will be planned for the following year. If the Quality Indicator report shows areas that are not satisfactory, then a corrective plan of action will be completed and a 6 months follow-up visit or phone call will be done.