

CHAPTER 37  
BREAST AND CERVICAL CANCER  
EARLY DETECTION PROGRAM

**641—37.1(135) Definitions.** For purposes of this chapter, the following definitions apply:

*“Abnormal screen”* means a suspicion of breast or cervical cancer.

1. A suspicion of breast cancer includes clinical breast exam findings of: palpable breast mass, breast dimpling, nipple retraction, bloody nipple discharge, palpable lymph nodes around clavicle or axilla, nipple erythema and scaliness, a mammography result of breast imaging reporting and data systems (BI-RADS) category 4 (suspicious abnormality suggesting need for biopsy) or category 5 (highly suggestive of malignancy) (ICD-9 793.8), breast biopsy result of ductal cancer in situ, lobular cancer in situ (ICD-9 233.0), or breast or lymph node (or other) biopsy result of breast cancer.

2. Suspicion of cervical cancer is a Pap test result of atypical squamous cells cannot exclude high-grade squamous intraepithelial lesions (ASC-H) (ICD-9 795.02), atypical glandular cells (AGC) (ICD-9 795.00), low-grade squamous intraepithelial lesions (LSIL) (ICD-9 622.11 or 795.03), or high-grade squamous intraepithelial lesions (HSIL) (ICD-9 622.12 or 795.04), leukoplakia of the cervix (ICD-9 622.2), or cervical biopsy result of cervical intraepithelial neoplasia II or III (ICD-9 622.10, 622.11, 622.12, 795.03, or 795.04), or cancer in situ (ICD-9 233.1).

*“Advanced registered nurse practitioner”* means an individual licensed to practice under 655 Iowa Administrative Code Chapter 7.

*“American College of Radiology”* or *“ACR”* means one of the Food and Drug Administration-recognized accreditation bodies for minimum quality standards for personnel, equipment, and record keeping in facilities that provide mammography.

*“Benign”* means a noncancerous condition that does not spread to other parts of the body.

*“Bethesda system”* or *“TBS”* means a system that was developed to provide uniform diagnostic terminology for reporting cervical or vaginal cytologic findings to facilitate communication between the laboratory and the clinician.

*“Biopsy”* means the removal of a sample or an entire abnormality for microscopic examination to diagnose a problem. Examples of a sampling would be a core biopsy or incisional biopsy; an example of entire removal would be an excisional biopsy.

*“Breast image reporting and data systems”* or *“BI-RADS”* means a standardized reporting system for mammography reports.

*“Breast ultrasound”* means the use of high-energy sound waves that are bounced off internal tissues and make echoes to produce a pictorial representation of the internal structure of the breast.

*“Cancer”* means a malignant tumor of potentially unlimited growth of new cells that expand locally by invasion and systemically by metastasis.

*“Carcinoma in situ”* means cell changes in which malignant cells are localized and may press against adjoining tissue but have not penetrated or spread beyond their site of origin.

*“Case management”* means the IA BCCEDP component that involves establishing, brokering, and sustaining a system of available clinical and essential support services for all women enrolled in the program.

*“Clinical breast examination”* or *“CBE”* means complete examination of a woman’s breast and axilla with palpation, including examination of the breast in both the upright and supine positions by a health care provider.

*“Clinical Laboratory Improvement Act of 1988”* or *“CLIA”* means the law which established minimum quality standards for personnel and quality assurance methods that monitor patient test management and assess quality control, proficiency testing, and personnel handling of laboratory and pathology specimens.

*“Colposcopy”* means a procedure that allows close examination of the surface of the cervix with a high-powered microscope.

“*Cooperative agreement*” means a signed contract between the department and another party, for example, a health care provider. This contract allows the department to pay the health care provider for providing services to IA BCCEDP participants.

“*Creditable coverage*” means any insurance that pays for medical bills incurred for the screening, diagnosis, or treatment of breast and cervical cancer. Creditable coverage as described by the Health Insurance Portability and Accountability Act of 1996 includes, but is not limited to, group health plans or health insurance coverage consisting of medical care under any hospital or medical service policy, health maintenance organization, Medicare Part A or B, Medicaid, armed forces insurance, or state health risk pool. A woman who has creditable coverage shall not be eligible for the Medicaid coverage option of breast and cervical cancer treatment.

“*Creditable coverage circumstances*” means those instances in which a woman has creditable coverage but is not actually covered for treatment of breast or cervical cancer.

1. When there is a preexisting-condition exclusion or when the annual or lifetime limit on benefits has been exhausted, a woman is not considered to have creditable coverage for this treatment.

2. If the woman has limited coverage, such as a high deductible, limited drug coverage, or limits on the number of outpatient visits, the woman is still considered to have creditable coverage and is not eligible for coverage under the breast and cervical cancer treatment (BCCT) option of Medicaid.

3. If the woman has a policy with a limited scope of coverage, such as only dental, vision, or long-term care, or has a policy that covers only a specific disease or illness, she is not considered to have creditable coverage, unless the policy provides coverage for breast and cervical cancer treatment.

4. For the purposes of this program, eligibility for Indian Health Services or tribal health care is not considered creditable coverage (according to United States Senate File 1741 – Native American Breast and Cervical Cancer Treatment Technical Amendment Act of 2001).

“*Cytology*” means the scientific study of cells.

“*Cytopathology*” means the scientific study of cells in disease.

“*Cytotechnologist*” means a medical technician trained in the identification of cells and cellular abnormalities.

“*Department*” means the Iowa department of public health.

“*Diagnostic mammography*” means a radiological examination performed for appropriate clinical indications such as breast mass(es), other breast signs or symptoms (spontaneous nipple discharge, skin changes), or special cases, such as a history of breast cancer with breast conservation or augmented breasts.

“*Follow-up*” means the IA BCCEDP component that involves a system for seeking information about or reviewing an abnormal condition, rescreening, or recall for annual visits.

“*Food and Drug Administration*” or “*FDA*” means the federal governmental body which certifies that a mammography facility meets minimum quality standards for personnel, equipment, and record keeping.

“*Gynecologist*” means a physician who specializes in diseases of the reproductive organs in women.

“*Health care provider*” means any physician, advanced registered nurse practitioner, or physician assistant who is licensed by the state of Iowa and provides care to IA BCCEDP-enrolled women.

“*Infrastructure*” means the basic framework of sufficient staff and adequate support systems to plan, implement, and evaluate the components of the IA BCCEDP.

“*In need of treatment*” means that a medical or surgical intervention is required because of an abnormal finding of breast or cervical cancer or precancer that was determined as a result of a screening or diagnostic procedure for breast or cervical cancer/precancer under the NBCCEDP.

“*International Classification of Disease, 9th edition*” or “*ICD-9*” means a standardized classification of diseases, injuries, and reasons of death, by cause and anatomic localization and systematically put into a number of up to six digits, which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both in the United States and internationally.

“*Iowa breast and cervical cancer early detection program*” or “*IA BCCEDP*” means a comprehensive breast and cervical cancer screening program established and funded under Title XV of the federal Public Health Service Act and administered by the Iowa department of public health, with

the delegated responsibility of implementation and evaluation from the Centers for Disease Control and Prevention, Division of Cancer Prevention and Control.

*“Medicaid”* means the program of medical aid designed for those unable to afford regular medical service, financed by federal and state payment sources, and authorized by Title XIX of the Social Security Act.

*“Medical advisory task force”* or *“MATF”* means an advisory board utilized by the IA BCCEDP to offer knowledge and experience as related to the fields of expertise of the members of the task force. Duties of the MATF may include, but are not limited to, the following:

1. Review and make recommendations for clinical service expansion.
2. Review of program-developed clinical protocols.
3. Provision of recommendations related to other clinical and client-related issues.
4. Input related to quality assurance issues.
5. Review of program screening and diagnostic data.

*“Medicare”* means the program of federal payment source for health benefits, especially for the aged, that is authorized by Title XVIII of the Social Security Act.

*“Minimum data elements”* or *“MDEs”* means a set of standardized data elements used to collect demographic and clinical information on women whose screening or diagnosis was paid for with NBCCEDP funds. MDEs were developed by the Centers for Disease Control and Prevention, Division of Cancer Prevention and Control, to ensure that consistent and complete information is collected on women whose screening or diagnosis was paid for with NBCCEDP funding.

*“National breast and cervical cancer early detection program”* or *“NBCCEDP”* means a program established with the passage of the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354). The law authorizes the Centers for Disease Control and Prevention to establish a program of grants to states, tribes, and territories for the purpose of increasing the early detection of breast and cervical cancer, particularly among low-income, uninsured, and underserved women.

*“Oncologist”* means a physician who is a specialist who treats or studies the physical, chemical, and biologic properties and features of neoplasms, including causation, pathogenesis, and treatment.

*“Outreach”* means the IA BCCEDP component that involves recruiting targeted populations or persons who never or rarely utilize preventive health services.

*“Pap test”* means a screening test that collects cells from the cervix for examination under a microscope. The Pap test can detect abnormal cells or precancerous cells before cancer develops.

*“Pathologist”* means a physician who is a specialist in identifying diseases by studying cells and tissues under a microscope.

*“Physician”* means an individual licensed to practice under Iowa Code chapter 148.

*“Physician assistant”* means an individual licensed to practice under Iowa Code chapter 148C.

*“Precancerous”* means a condition that may become or is likely to become cancer.

*“Program and fiscal management”* means the IA BCCEDP component that conducts planning, organizing, directing, coordinating, managing, budgeting, and evaluating program activities.

*“Radiologist”* means a physician who specializes in creating and interpreting pictures of areas inside the body. The pictures are produced with X-rays, sound waves, or other types of energy.

*“Rarely been screened”* means, as defined for the NBCCEDP, that a woman has not had cervical cancer screening within the last five years.

*“Recruitment”* means the IA BCCEDP component that involves enrolling targeted populations or persons who never or rarely utilize preventive health services.

*“Referral”* means the IA BCCEDP component that involves directing women with abnormal screening results to appropriate resources for follow-up action.

*“Screening mammography”* means the use of X-ray of the breasts of asymptomatic women in an attempt to detect abnormal lesions of the breast when they are small, nonpalpable, and confined to the breast.

*“Service delivery”* means providing, either directly or through contractual arrangements, comprehensive breast and cervical cancer screening, diagnosis, and treatment services through tracking of screening intervals, timeliness of diagnosis, and timeliness of treatment of clients.

“*Surgeon*” means a physician who treats disease, injury, or deformity by physical operation or manipulation.

“*Surveillance*” means the IA BCCEDP component that involves the systematic collection, analysis, and interpretation of health data.

“*Susan G. Komen for the Cure*” means an international organization with a network of volunteers working through local affiliates and Komen Race for the Cure® events to eradicate breast cancer as a life-threatening disease by advancing research, education, screening, and treatment.

[ARC 7670B, IAB 4/8/09, effective 5/13/09]

**641—37.2(135) Components of the IA BCCEDP.** The IA BCCEDP shall include the following key components:

**37.2(1)** Program and fiscal management shall be conducted by ensuring strategic planning, implementation, coordination, integration, and evaluation of all programmatic activities and administrative systems, as well as the development of key communication channels and oversight mechanisms to aid in these processes. Program management shall ensure that infrastructure adequately supports service delivery.

**37.2(2)** Service delivery of specific and appropriate clinical procedures to detect breast and cervical abnormalities for women enrolled in the IA BCCEDP shall be directly provided or provided through contractual arrangements.

*a.* IA BCCEDP shall cover services including, but not limited to, the following when those services are provided by a participating health care provider who has a signed cooperative agreement with IA BCCEDP. Payment shall be based on Medicare Part B rates (Title XIX).

(1) Physical examinations, which must include one or more of the following screening services: CBE, pelvic exam, or Pap test;

(2) Mammography (screening and diagnostic);

(3) Breast ultrasound, when used as an adjunct to mammography;

(4) Fine-needle aspiration of breast cysts;

(5) Breast biopsies, excisional and nonexcisional (physician charges only; hospital charges are not covered);

(6) Colposcopy of the cervix, with or without biopsy;

(7) Surgical consultations for diagnosis of breast and cervical cancer;

(8) Pathology charges for breast and cervical biopsies;

(9) Anesthesia for breast biopsies (health care provider charges only; hospital charges and supplies are not covered).

*b.* Services not covered by IA BCCEDP include, but are not limited to, the following:

(1) Services not related to breast or cervical cancer screening or diagnosis;

(2) Treatment procedures and services;

(3) Services provided by nonparticipating providers;

(4) Hospital charges for breast biopsies and anesthesia;

(5) Inpatient services.

*c.* A health care provider who has a signed cooperative agreement with the IA BCCEDP shall be subject to the following:

(1) The health care provider agrees that reimbursement of procedures and services provided shall not exceed the amount that would be paid under Medicare Part B rates of Title XVIII of the Social Security Act;

(2) A mammography health care provider shall ensure that the provider’s facility has current FDA certification and ACR or state of Iowa accreditation and is a Medicare and Medicaid-approved facility utilizing BI-RADS and following ACR guidelines for mammography report content;

(3) A board-certified radiologist must be immediately available to determine selection of views and readings when a diagnostic mammogram is performed;

(4) The health care provider shall submit cytology and pathology specimens obtained to a CLIA-certified laboratory for processing. The laboratory shall provide cytological reading and analysis

of cervical and vaginal Pap tests by certified/registered cytotechnologists. Cytology (Pap) tests shall be reported using current TBS. The laboratory shall provide board-certified pathologists or experienced certified cytotechnologists to rescreen all analyses and readings of cervical and breast biopsies;

(5) The health care provider shall practice according to the current standards of medical care for breast and cervical cancer early detection, diagnosis, and treatment;

(6) Service delivery may be provided in a variety of settings. Service delivery must, however, include:

1. Providing screening services for specific geographic areas;
2. Providing a point of contact for scheduling appointments;
3. Providing age and income eligibility screening;
4. Providing comprehensive breast and cervical cancer screening to eligible women;
5. Providing referral and follow-up for women with abnormal screening results;
6. Providing the required reporting system for screening and follow-up activities;
7. Providing population-based education, outreach, and recruitment activities;

(7) The health care provider shall ensure compliance with this chapter and other terms and conditions included in the signed cooperative agreement.

**37.2(3)** Referral, tracking, and follow-up utilizing a data system to monitor each enrolled woman's receipt of screening/rescreening, diagnostic, and treatment procedures shall be conducted by IA BCCEDP and contracted county board of health designated agency staff.

*a.* The enrolled woman shall be notified by contracted county board of health designated agency staff of the results of the service, whether the results are normal, benign, or abnormal.

*b.* The data system shall provide tracking of appropriate and timely clinical services following an abnormal test result or diagnosis of cancer.

*c.* If the enrolled woman has an abnormal Pap test or breast screening, the health care provider shall provide to the woman a comprehensive referral directing her to appropriate additional diagnostic or treatment services.

*d.* The comprehensive referral shall be written. Follow-up shall be conducted to determine whether services were timely, completed, or met.

**37.2(4)** IA BCCEDP and contracted county board of health designated agency staff shall provide case management and assist clients diagnosed with cancer through the program to obtain needed treatment services.

**37.2(5)** IA BCCEDP staff shall use quality assurance and improvement techniques including use of established standards, systems, policies and procedures to monitor, assess and identify practical methods for improvement of the program and its components.

*a.* Quality assurance tools shall include utilizing FDA and ACR minimum standards for mammography facilities and CLIA minimum standards for cytopathology and pathology laboratories.

*b.* Quality assurance measures shall contribute to the identification of corrective actions to be taken to remedy problems found as a result of investigating quality of care.

**37.2(6)** Professional development shall be provided by IA BCCEDP and contracted county board of health designated agency staff through a variety of channels and activities that enable professionals to perform their jobs competently, identify needs and resources, and contribute to ensuring that health care delivery systems provide positive clinical outcomes.

**37.2(7)** IA BCCEDP and contracted county board of health designated agency staff shall provide population-based education and recruitment that involve the systematic design and delivery of clear and consistent messages about breast and cervical cancer and the benefits of early detection, using a variety of methods and strategies to reach priority populations. Outreach activities should focus on women who have never or rarely been screened and should work toward the removal of barriers to care (i.e., the need for child care, respite care, interpreter services and transportation) through collaborative activities with other community organizations.

**37.2(8)** IA BCCEDP may develop coalitions and partnerships to bring together groups and individuals that establish a reciprocal agreement for sharing resources and responsibilities to achieve the common goal of reducing breast and cervical cancer mortality.

**37.2(9)** IA BCCEDP shall conduct surveillance utilizing continuous, proactive, timely and systematic collection, analysis, interpretation and dissemination of breast and cervical cancer screening behaviors and incidence, prevalence, survival, and mortality rates. Epidemiological studies shall be conducted utilizing minimum data elements and other data sources to establish trends of disease, diagnosis, treatment, and research needs. Program planning, implementation, and evaluation shall be based on the epidemiological evidence.

**37.2(10)** Evaluation of the program shall be conducted through systematic documentation of the operations and outcomes of the program, compared to a set of explicit or implicit standards or objectives.

*a.* MATF shall review the service delivery contractual agreements as to their outcomes.

*b.* MATF shall make recommendations based on the evaluation in its annual report.

[ARC 7670B, IAB 4/8/09, effective 5/13/09]

**641—37.3(135) Client eligibility criteria.** An applicant for IA BCCEDP must satisfy the criteria outlined in this rule. If a woman does not meet these criteria, she shall be provided information by contracted county board of health designated agency staff regarding IowaCare, free care, or sliding-fee clinics available in the area in which she lives.

**37.3(1) Age.** An applicant for IA BCCEDP must satisfy only one of these criteria.

*a.* Women 50 through 64 years of age shall be the priority population to receive annual breast and cervical (if appropriate) cancer screening.

*b.* Women 40 through 49 years of age shall receive annual breast and cervical (if appropriate) cancer screening.

*c.* If symptomatic for breast cancer, women under 40 years of age shall receive services.

*d.* Women 65 years of age and older shall be eligible to receive annual breast and cervical (if appropriate) cancer screening if they do not have Medicare Part B coverage.

**37.3(2) Income.**

*a.* IA BCCEDP income guidelines are based upon 250 percent of the federal poverty level, which is set annually by the Centers for Medicare and Medicaid Services (CMS). New IA BCCEDP income guidelines will be adjusted following any change in CMS guidelines.

*b.* Self-declaration of income may be accepted.

*c.* Eligibility shall be based on net income for the household.

*d.* Assets shall not affect income status and shall not be counted when eligibility under the IA BCCEDP is determined.

**37.3(3) Insurance.**

*a.* IA BCCEDP shall determine a woman to be uninsured if the woman does not have health insurance coverage.

*b.* IA BCCEDP shall determine a woman to be underinsured if the woman has health insurance with unreasonably high copayments, deductibles, or coinsurance or the insurance does not cover IA BCCEDP-covered services.

*c.* Women who have Medicaid or Medicare Part B are not eligible. EXCEPTIONS: IowaCare, Medicaid with spenddown, Iowa family planning network.

**37.3(4) Residency.**

*a.* A woman must be a resident of Iowa or of a state that shall enroll a woman in the BCCT option of Medicaid if screened or diagnosed by the IA BCCEDP.

*b.* A woman who is a resident of a state that does not accept women into the BCCT option of Medicaid and who chooses to continue to receive services in the IA BCCEDP must be informed that she may not be able to have her treatment paid for by the BCCT option of Medicaid if she does not receive services in her state of residence.

*c.* Proof and length of residency in Iowa are not required.

**37.3(5) Ineligible.** IA BCCEDP does not provide coverage for:

*a.* Men.

*b.* Women with Medicare Part B coverage.

c. Women 39 years of age and younger unless they have symptoms of breast cancer.  
[ARC 7670B, IAB 4/8/09, effective 5/13/09]

**641—37.4(135) Client application procedures for IA BCCEDP services.**

**37.4(1) Enrollment.** After a woman is determined eligible for services:

a. The woman must complete, sign, and return a consent and release form to IA BCCEDP. The date on the signed form shall be the client's enrollment date.

b. Upon enrollment, the client must select an IA BCCEDP health care provider and is eligible for services for 12 months from the enrollment date, subject to restrictions in program coverage as provided in rule 641—37.5(135).

c. If a client is unable to access a particular health care provider due to unavailability of appointments or if a client requests to change to another health care provider, designated agency staff shall assist the client in choosing another IA BCCEDP health care provider who is available in the client's area.

**37.4(2) Reenrollment.**

a. A client's continued eligibility for program coverage shall be determined annually.

b. No more than 45 days prior to the end of the 12-month coverage period, IA BCCEDP shall contact the client to see if she wishes to reenroll in the program.

c. If a client wishes to reenroll, she must complete, sign and return a consent and release form before receiving any further services.

**37.4(3) Termination of enrollment.** IA BCCEDP shall terminate a client's enrollment if the client:

a. Requests termination from the program;

b. No longer meets the criteria set forth in rule 641—37.3(135);

c. Does not return a signed IA BCCEDP consent and release form; or

d. Refuses to receive screening and diagnostic services through an IA BCCEDP health care provider.

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**641—37.5(135) Priority for program expenditures.**

**37.5(1)** In the event the IA BCCEDP program director certifies that there are inadequate funds to meet clients' needs, either attributable to a reduction in federal funding from the CDC or to a projected enrollment of women in excess of anticipated enrollment, the program director may restrict new applicants' participation in IA BCCEDP as follows:

a. First priority shall be given to women 50 through 64 years of age.

b. Second priority shall be given to women 40 through 49 years of age who are symptomatic.

c. Third priority shall be given to women 40 through 49 years of age who are asymptomatic.

d. Fourth priority shall be given to women 65 years of age and older if they do not have Medicare Part B coverage.

**37.5(2)** In the event that the financial demand abates, the program director shall withdraw the financial shortfall certification, at which time women shall be eligible for program services in accordance with rule 641—37.3(135).

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**641—37.6(135) Right to appeal.** If an individual disagrees with or is dissatisfied with program eligibility, the covered-service determination, or the decision of the program, the individual has the right to appeal the decision or action.

**37.6(1)** The appeal shall be in writing and shall be submitted to the designated agency personnel with whom the individual has been working, within ten working days of the decision or action.

**37.6(2)** The designated agency staff shall contact a state IA BCCEDP staff person with the information regarding the appeal.

**37.6(3)** State IA BCCEDP staff shall confer with the bureau chief of the department and provide a decision to the designated agency staff within five business days. A decision made by state IA BCCEDP staff shall be delivered by telephone, if possible, to the individual making the appeal and shall be followed

by a written notification of the decision. The decision of state IA BCCEDP staff shall be considered a final agency decision in accordance with Iowa Code chapter 17A.

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**641—37.7(135) Verification for breast or cervical cancer treatment (BCCT) option of Medicaid.** The Iowa department of public health and the department of human services have coordinated to develop procedures for women to access Medicaid coverage for treatment of breast or cervical cancer.

**37.7(1)** Before referring a woman to her county of residence's local office of the department of human services, a contracted county board of health designated agency staff member shall document the following regarding the woman:

*a.* The woman is currently enrolled in the IA BCCEDP. To be considered enrolled in the program, the woman must meet program age guidelines, have at least one of the basic screening services (Pap test, screening mammogram, or CBE) or diagnostic procedures paid by the IA BCCEDP or with Susan G. Komen for the Cure funds, and be in need of treatment for breast or cervical cancer or precancerous conditions; or

*b.* The woman was enrolled in NBCCEDP and has moved to Iowa. To be considered enrolled in NBCCEDP, the woman must meet the Iowa program age guidelines, have at least one of the basic screening services (Pap test, screening mammogram, or CBE) or a diagnostic procedure paid by the NBCCEDP or with Susan G. Komen for the Cure funds, and be in need of treatment for breast or cervical cancer or precancerous conditions; and

*c.* The woman has creditable coverage circumstances or has no creditable health insurance for breast or cervical cancer treatment.

**37.7(2)** The BCCT option of Medicaid is administered by the Iowa department of human services under 441 Iowa Administrative Code Chapter 75, "Conditions of Eligibility."

These rules are intended to implement Iowa Code chapter 135.

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