



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

Larry Hogan, Governor - Boyd K. Rutherford, Lt. Governor - Dennis R. Schrader, Secretary

March 7, 2017

Dear Maryland Breast and Cervical Cancer Provider:

**Maryland Breast & Cervical
Cancer Program Medical
Advisory Committee**

Breast Cancer Subcommittee

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Thank you for providing breast cancer screening for uninsured or underinsured women aged 40-64 enrolled in the Maryland Breast and Cervical Cancer Program (BCCP). The Maryland BCCP is a grantee of the National Breast and Cervical Cancer Early Detection Program, funded by the Centers for Disease Control and Prevention. The policies of the national program are based on evidence in scientific literature and recommendations from national organizations such as the American Cancer Society, the United States Preventive Services Task Force, the National Comprehensive Cancer Network and the American College of Radiology.

We are pleased to enclose the revised "Minimal Clinical Elements for Breast Cancer Detection and Diagnosis" developed by the Medical Advisory Committee for the BCCP to serve as guidelines for the management of women receiving breast cancer screening and diagnostic services through the BCCP.

The revision includes when breast tomosynthesis (3D mammogram) is reimbursable in the Maryland BCC Program.

We appreciate your cooperation in using the new guidelines. If you have any questions regarding the new "Minimal Clinical Elements for Breast Cancer Detection and Diagnosis" for the Maryland Breast and Cervical Program, please contact Ken Lin Tai, M.D., M.P.H., Medical Director for the Center for Cancer Prevention and Control (CCPC) at 410-767-2036 or kenlin.tai@maryland.gov.

Sincerely,

Stanley Watkins, M.D.

Chairman, Medical Advisory Committee

Maryland Breast and Cervical Cancer Program

Enclosure

Cc Ken Lin Tai, MD, MPH, Medical Director/Acting Director, CCPC
Holly Harshbarger, RN, BS, Program Nurse Consultant, BCCP
Local BCCP Coordinators

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Minimal Clinical Elements for Breast Cancer Detection and Diagnosis
Maryland Breast and Cervical Cancer Program
Maryland DHMH, Center for Cancer Prevention and Control
March 2017

Goal:

The goal of the Minimal Clinical Elements for Breast Cancer Detection and Diagnosis is to provide clients of the Maryland Breast and Cervical Cancer Program (BCCP) with optimal, up-to-date screening for breast cancer and management of findings

Objective:

- To provide clinical guidelines for breast cancer screening and diagnostic testing including interpretation and management of results of clinical breast examination, mammography, and diagnostic testing.
- To outline appropriate management and approved indications for procedure payment.

Detection and Management of Breast Abnormalities in the Breast and Cervical Cancer Program—Breast Cancer Minimal Clinical Elements

Section	Page
I. Maryland Breast and Cervical Cancer Program (BCCP)— Eligibility for Screening, Procedures for Screening or Initial Testing, and Eligibility for Diagnostic Testing when referred by a clinician for follow-up for an abnormal breast screening exam.	
A. BCCP Eligibility and Procedures for Screening or Initial Testing	3
B. Eligibility for Diagnostic Testing in the BCCP	4
II. Findings, Management of Results, Additional Procedures and Program Coverage	
A. Results and Reports	5
B. Management of Findings of CBE, Initial Mammogram, and Testing	6
C. Additional Procedures and Program Coverage	6
Attachment A	9
Flow Charts of the Maryland Breast and Cervical Cancer Program: Management of Clinical Breast Examination and Mammogram Results	
I. Management when the Clinical Breast Exam is <i>Normal/Benign</i>	10
II. Management when the Clinical Breast Exam is <i>Abnormal</i>	11

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Detection and Management of Breast Abnormalities in the Breast and Cervical Cancer Program

Breast Cancer Minimal Clinical Elements (MCE)

I. Maryland Breast and Cervical Cancer Program (BCCP)—Eligibility for Screening, Procedures for Screening or Initial Testing, and Eligibility for Diagnostic Testing When Referred by a Clinician for Follow-up for an Abnormal Breast Screening Exam

A. BCCP Eligibility and Procedures for Screening or Initial Testing

1. A woman is eligible for breast cancer screening with clinical breast examination (CBE) and mammogram¹ in the BCCP *regardless* of symptoms, risk factors, or prior breast cancer/findings if she:
 - a. Is 40 – 64 years old or 65+ without Medicare Part B;
 - b. Meets income eligibility of household income $\leq 250\%$ of the Federal Poverty Guideline;
 - c. Has no health insurance, has health insurance that does not cover breast cancer screening, or has health insurance but has not met the deductible for the year, and/or has a patient contribution amount for applicable procedures to include copays and co-insurance; **and**
 - d. Has **not** had bilateral mastectomies.

2. A woman should have a **diagnostic mammogram** if a woman has:
 - a. A CBE with results that include:
 - i. Nipple discharge that is:
 - (a) Bloody;
 - (b) Crystal clear (like water); or
 - (c) Any other color or clarity (for example, yellow, white, milky, gray, green) if the discharge is unilateral, single duct, and spontaneous.
 - ii. Discrete palpable mass—suspicious for cancer;
 - iii. Nipple/areolar scaliness; or
 - iv. Skin dimpling/retraction;
 - b. A recommendation for a diagnostic mammogram from the Medical Case Manager.

3. A woman should have a **screening mammogram** as the annual exam if the woman has:
 - a. A CBE with Normal findings or a CBE with Benign findings, including:
 - i. Nipple discharge that does not meet the requirement for diagnostic mammogram (2., a., i., above);
 - ii. Breast implant(s);
 - iii. Fibrocystic changes,
 - iv. Mastitis;

¹ See page 6, section C, #2 for guidance regarding the type of mammogram allowable in the Maryland BCCP.

- v. “Lumpy” breasts;
 - vi. Family history of breast cancer (premenopausal breast cancer in sister/mother);
or
 - vii. Prior benign biopsy (within past year) when surgeon or radiologist recommends screening mammogram.
- b. A history of negative screening mammogram(s) (American College of Radiology, Breast Imaging and Database Reporting System [BI-RADS] category 1, negative, or BI-RADS 2, benign finding).
4. A woman with a prior history of breast cancer (in situ or invasive, in patient who has not had bilateral mastectomies) should have a:
 - a. Diagnostic mammogram for 5 years post diagnosis then;
 - b. May resume screening mammogram after 5 years at the discretion of the medical case manager, radiologist and client.
 5. CBE should be performed within 90 days prior to the screening mammogram.
 - a. Each breast should be examined including the retroareolar and peripheral areas and the upper lateral quadrant into the axilla.
 - b. The preferred method of CBE is the strip technique using three levels of pressure in small circular motions with pad of three middle fingers without lubrication (MammaCare® method).

B. Eligibility for Diagnostic Testing in the BCCP

A woman is eligible for breast cancer diagnostic testing **in the BCCP** if she:

1. Is 40 – 64 years old, or 65+ without Medicare Part B;
2. Meets income eligibility of $\leq 250\%$ of the Federal Poverty Guideline;
3. Has no health insurance, has health insurance that does not cover breast cancer diagnostic testing/visits, or has health insurance but has not met the deductible for the year, and/or has a patient contribution amount for applicable procedures to include copays and co-insurance.
4. Has not had bilateral mastectomies; and
5. Provides the BCCP with a recommendation from a clinician for diagnostic workup and test results of:
 - a. CBE requiring further diagnosis (see I. A. 2. a.);
 - b. Mammogram requiring further diagnosis;
 - c. Ultrasound abnormal finding other than simple cyst(s); or
 - d. Persistent, unexplained, localized pain in the breast with a negative mammogram.

II. Findings, Management of Results, Additional Procedures, and Program Coverage

A. Results and Reports

1. CBE findings:

a. Should be reported as:

i. Normal exam

ii. Benign findings

iii. Abnormal findings:

1. Nipple discharge that is bloody, crystal clear (like water) or any other color or clarity (for example, yellow, white, milky, gray, green) if the discharge is unilateral, single duct, and spontaneous.

2. Discrete palpable mass—suspicious for cancer

3. Nipple/areolar scaliness

4. Skin dimpling/retraction

b. CBE should report whether there are breast implants; however, this finding would be categorized as a “Benign finding” if no other abnormalities were found.

c. CBE should report whether the patient has had a lumpectomy or a mastectomy and which breast was affected; however, this finding would be categorized as a “Benign finding” if no other abnormalities were found.

2. Mammogram findings should be reported using American College of Radiology BI-RADS® (Breast Imaging-Reporting and Database System) Assessment Categories:

a. Assessment is Incomplete

0 Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison

b. Assessment is Complete – Final Categories

1 Negative

2 Benign Finding(s)

3 Probably Benign Finding – Initial Short-Interval Follow-Up Suggested

4 Suspicious Abnormality – Biopsy Should Be Considered

5 Highly Suggestive of Malignancy – Appropriate Action Should Be Taken

6 Known Biopsy-Proven Malignancy – Appropriate Action Should Be Taken

(Category reserved for lesions identified on imaging study with biopsy proof of malignancy prior to definitive therapy)

Ref. The American College of Radiology BI-RADS® ATLAS and MQSA: Frequently Asked Questions (Updated: 7/1/09)

c. Breast composition on mammogram should be described for all patients using the following patterns:

i. The breasts are almost entirely fatty

ii. There are scattered areas of fibroglandular density

iii. The breasts are heterogeneously dense, which may obscure small masses

iv. The breasts are extremely dense, which lowers the sensitivity of mammography

Ref. 2013 ACR® BI-RADS Atlas (5TH Edition)

3. **Ultrasound definitions:** The terms “simple cyst,” “complicated cyst,” and “complex cyst” are defined by the radiologist and stated in the report of an ultrasound examination.
4. The radiologist’s diagnostic workup/evaluation report should include the results of the diagnostic mammogram, ultrasound (when performed), CBE, and the correlation of each test with each other.

B. Management of Findings of CBE, Initial Mammogram, and Testing

1. **See Attachment A.** Flow Charts of the Maryland Breast and Cervical Cancer Program: Management of Clinical Breast Examination and Mammogram Results.
2. A woman with persistent, unexplained, localized pain in the breast should be evaluated by a breast specialist or surgeon.
3. If a radiologist recommends obtaining results or copies of prior mammograms following a BI-RADS category 0 result, local programs should assist in obtaining the results or copies.
4. Image-guided percutaneous needle biopsy is the diagnostic procedure of choice for image-detected abnormalities, with few exceptions.
5. When a non-palpable or questionably palpable mass that was found on imaging is excised, the specimen should be verified by using the appropriate imaging modality while the patient is still in the operating room.
6. At least one breast tissue specimen positive for cancer should be tested for tumor markers (e.g. estrogen/progesterone receptors, her2neu etc.) to guide clinical management.

C. Additional Procedures and Program Coverage

1. Providers should consult with the local BCCP for questions about coverage for payment of procedures.
2. Breast Tomosynthesis (3D mammography)
 - a. The Maryland BCCP will reimburse for breast tomosynthesis (3D mammogram) if the medical case manager or radiologist recommends the procedure.
 - b. The medical provider (medical case manager or radiologist) ordering the mammogram is responsible for discussing the use of 2D and/or 3D mammography and its benefits and risks in breast cancer screening with the woman.
3. Magnetic Resonance Imaging (MRI)
 - a. The Maryland BCCP will reimburse for screening breast MRI performed in conjunction with a mammogram when a client has the following indications:

- i. Lifetime risk of breast cancer of about 20% to 25% or greater, according to risk assessment tools that are based mainly on family history (e.g. BRCAPRO),
 - ii. Known BRCA1 or BRCA2 gene mutation,
 - iii. First-degree relative (parent, brother, sister, or child) with a BRCA1 or BRCA2 gene mutation, but have not had genetic testing themselves,
 - iv. Radiation therapy to the chest when they were between the ages of 10 and 30 years, or
 - v. Li-Fraumeni syndrome, Cowden syndrome, or Bannayan-Riley-Ruvalcaba syndrome, or have first-degree relatives with one of these syndromes.
 - b. Breast MRI can also be reimbursed:
 - i. When used to better assess areas of concern on a mammogram; **or**
 - ii. For evaluation of a client with a past history of breast cancer after completing treatment.
 - c. Breast MRI should never be done alone as a breast cancer screening tool.
 - d. The BCCP **will not reimburse** for MRI of the breast for:
 - i. Surveillance of breast findings (for example, the program will not reimburse for MRI follow-up every 3-6 months for a surgical consult of “benign findings”); or
 - ii. Evaluation of silicone breast implant integrity.
4. The BCCP will reimburse for a surgical or breast specialist consultation for a woman who has a negative mammogram but who has persistent, unexplained, localized pain in the breast.
 5. BCCP funds surgical consults or follow-up visits intended to confirm or rule out breast cancer when screening tests yield abnormal results. BCCP will:
 - a. Reimburse a maximum of two consults or visits to the same breast surgeon for the same breast problem (initial consultation plus a follow-up consultation).
 - b. Reimburse follow-up of post-operative/post-biopsy complications of infection, hematoma, etc., following a BCCP-funded biopsy.
 - c. Consider reimbursement on a case-by-case basis for follow-up surgical visits where the surgical pathology may be associated with recurrence or the presence of a more severe abnormality in the breast (e.g. certain types of atypia, phyllodes tumors) and the surgeon recommends short-term follow-up (every 3-6 months) for a maximum of 12 months.
 - d. Not reimburse for on-going surveillance for those cases in which the medical case manager or surgeon recommends frequent follow-up visits for surveillance based on a benign breast condition that is considered chronic and or based on a woman’s risk factors.
 6. The BCCP will reimburse for immunohistochemical (IHC) stains as indicated below:
 - a. When cancer is diagnosed on the biopsy: the BCCP will reimburse for IHC stains ordered by the clinician or pathologist.

- b. When cancer is suspected or needs to be ruled out: IHC should not be used reflexively to evaluate every breast biopsy. IHC is best used when ordered by the pathologist where IHC will clarify an ambiguous pathologic diagnosis. The most frequent use of this is where the pathologist wants to know whether an adenoma or papilloma harbors invasive disease, or whether the tumor is ductal or lobular. The BCCP will reimburse in these cases but may request more information to justify the use of IHC.

Attachment A

Flow Charts of the Maryland Breast and Cervical Cancer Program:

Management of Clinical Breast Examination and Mammogram Results

- I. Management when Clinical Breast Examination is Normal/Benign Findings**

- II. Management when Clinical Breast Examination is Abnormal**

Clinical Breast Examination: Normal or Benign Findings

Women who:
 - are asymptomatic; and
 - have implant(s), fibrocystic changes, mastitis, "lumpy" breasts, family history of breast cancer (premenopausal breast cancer in sister/mother), prior benign biopsy (within past year) when surgeon or radiologist recommends screening mammogram.

Women who have:
 - a prior history of breast cancer should have a diagnostic mammogram for 5 years post diagnosis then at the discretion of the medical case manager, radiologist and client;
 or
 - Medical Case Manager recommendation for Diagnostic Mammogram

Screening mammogram

Diagnostic mammogram

Mammogram Results

BI-RADS 0:
Needs additional imaging evaluation

BI-RADS 1: Negative
BI-RADS 2: Benign Finding

BI-RADS 3:
Probably benign--short interval follow-up suggested

BI-RADS 4: Suspicious Abnormality – Biopsy Should Be Considered
BI-RADS 5: Highly Suggestive of Malignancy – Appropriate Action Should Be Taken

Follow up per radiologist:
 - Diagnostic work-up (spot compression, magnification, special views, ultrasound, aspiration...)

Annual follow-up:
 CBE with screening mammogram (if asymptomatic)

Follow up per radiologist (usually 6 month repeat imaging)

Radiologist communicates findings to the patient, the referring physician

Follow-up based on revised BI-RADS category

See Bi-RADS 1, 2 or See Bi-RADS 3 or See Bi-RADS 4 or 5 above.

No cancer on **image-guided biopsy**; and Surgeon does **NOT** perform biopsy

Further follow-up per surgeon*

Cancer (invasive or DCIS) on prior **image-guided biopsy**; surgeon performs no additional biopsy

Management and Treatment of Cancer
 Surgeon stages and initially manages breast cancer;
 - Stage 0 must be offered oncologist consult
 - Stage 1-4 must see oncologist

Surgeon performs biopsy

Positive biopsy (invasive cancer or DCIS+)

BI-RADS 4 or 5 with:
 Negative biopsy OR biopsy that is LCIS or atypical ductal hyperplasia

Further follow-up per surgeon*

Image-guided biopsy

Positive biopsy (invasive cancer or DCIS)

BI-RADS 5: and Negative biopsy OR **BI-RADS 4 or 5** with biopsy that is LCIS or atypical ductal hyperplasia

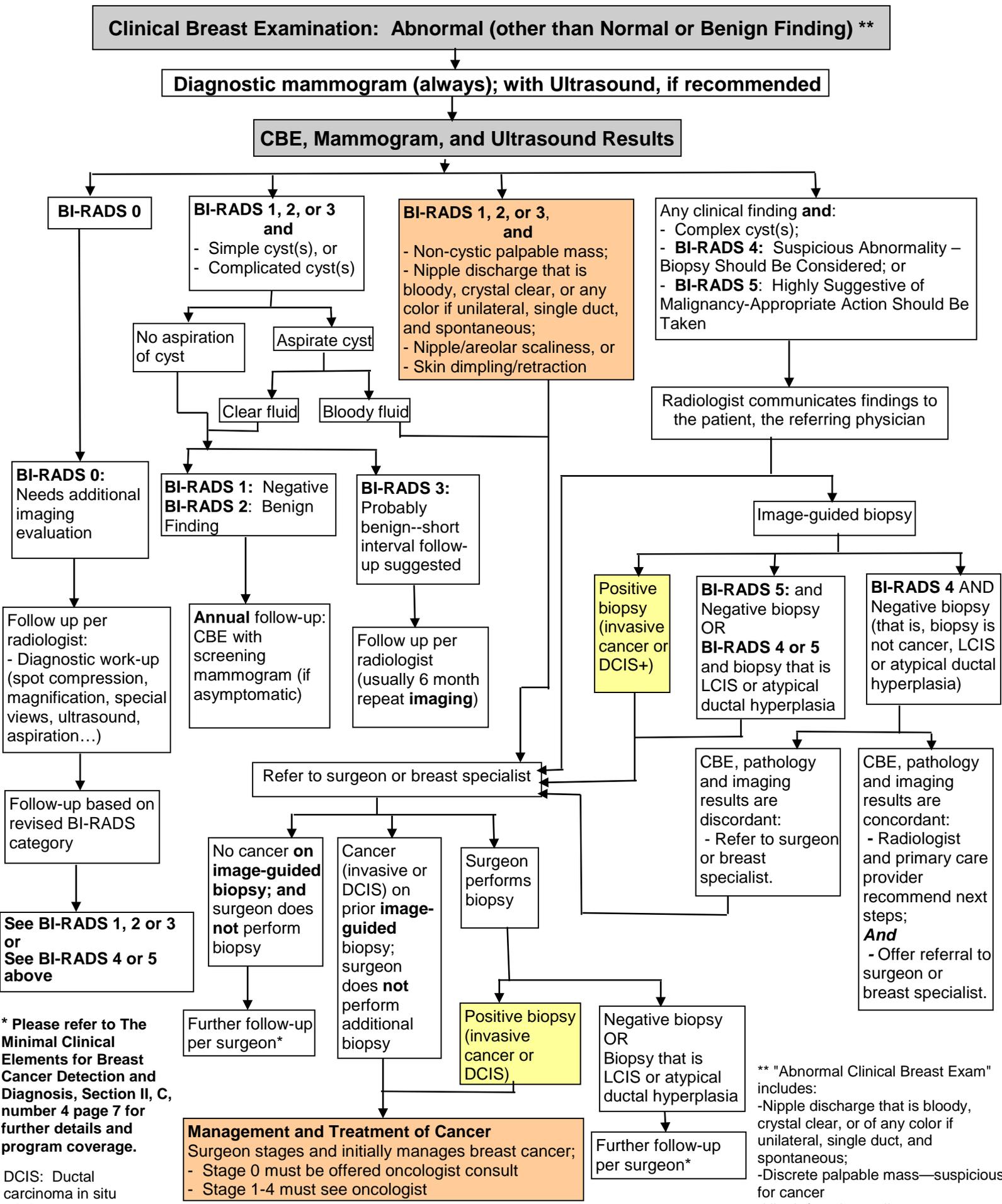
CBE, pathology and imaging results are discordant:
 - Refer to surgeon or breast specialist.

BI-RADS 4: AND Negative biopsy (that is, biopsy is not cancer, LCIS or atypical ductal hyperplasia)

CBE, pathology and imaging results are concordant:
 - Radiologist and primary care provider recommend next steps;
And
 - Offer referral to surgeon or breast specialist.

*Please refer to The Minimal Clinical Elements for Breast Cancer Detection and Diagnosis, Section II, C, number 4 page 7 for further details and program coverage.

DCIS: Ductal carcinoma in situ
 LCIS: Lobular carcinoma in situ



* Please refer to The Minimal Clinical Elements for Breast Cancer Detection and Diagnosis, Section II, C, number 4 page 7 for further details and program coverage.

DCIS: Ductal carcinoma in situ
LCIS: Lobular carcinoma in situ

** "Abnormal Clinical Breast Exam" includes:
-Nipple discharge that is bloody, crystal clear, or of any color if unilateral, single duct, and spontaneous;
-Discrete palpable mass—suspicious for cancer
-Nipple/areolar scaliness
-Skin dimpling/retraction