



STATE OF MARYLAND

DHMH

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November 23, 2009

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

Breast Cancer Subcommittee

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Dear Maryland Breast and Cervical Cancer Program Provider:

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 (CDC). 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 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 screening and management of women receiving breast cancer screening through the BCCP and diagnostic services through the BCCP Expanded.

The Minimal Clinical Elements were updated based in part on the American Cancer Society Guidelines for Breast Cancer Screening, the National Comprehensive Cancer Network Breast Cancer Screening and Diagnosis Guidelines, and evidence based reviews of Breast Magnetic Resonance Imaging. They were completed before the November 17, 2009 release of the U. S. Preventive Services Task Force (USPSTF) Recommendation Statement on Screening for Breast Cancer. Despite the USPSTF Recommendations, the enclosed November 2009 Minimal Clinical Elements for Breast Cancer Detection and Diagnosis serve as the recommendations for the Maryland BCCP until further notice.

Some of the major changes include:

- Specific guidelines for when a woman should receive a screening mammogram versus a diagnostic mammogram;
- Clarification of the use of Magnetic Resonance Imaging (MRI) within BCCP.
- New Flow Sheets for management of findings

Enclosed are the revised **“Minimal Clinical Elements for Breast Cancer Detection and Diagnosis.”**

We appreciate your cooperation in using these 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 Cancer Program, please contact Diane Dwyer, M.D., Medical Director of the Center for Cancer Surveillance and Control (CCSC) at (410) 767-5088 or ddwyer@dnhm.state.md.us.

Sincerely,



Stanley Watkins, M.D.

Chairman, Medical Advisory Committee

Maryland Breast and Cervical Cancer Program

Enclosure

cc: Donna Gugel, M.H.S., Director, CCSC
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Minimal Clinical Elements for Breast Cancer Detection and Diagnosis
Maryland Breast and Cervical Cancer Program
Maryland DHMH, Center for Cancer Surveillance and Control

November 2009

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

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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 Expanded Diagnostic Testing

A. BCCP Eligibility, and Procedures for Screening or Initial Testing (See also Attachment B)

1. A woman is eligible for breast cancer screening with clinical breast examination (CBE) and mammogram 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 no health insurance that covers breast cancer screening, or has coverage but has not met deductible for the year; **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. Prior unilateral mastectomy;
 - c. Prior history of breast cancer (in situ or invasive, in patient who has not had bilateral mastectomies); **or**
 - d. 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 doesn't meet the definition for diagnostic mammogram (2., a., i., above);
 - ii. Breast implant(s);
 - iii. Fibrocystic changes,
 - iv. Mastitis;

- 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);
 - c. No prior mastectomy; **and**
 - d. No prior breast cancer.
4. CBE should be performed within the three months prior to the screening mammogram.
 5. Each breast should be examined including the retroareolar and peripheral areas and the upper lateral quadrant into the axilla.
 6. 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 Expanded Services

A woman or man is eligible for breast cancer diagnostic testing **in the BCCP Expanded Services** if s/he:

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 no health insurance that covers breast cancer diagnostic testing/visits, or has coverage but has not met deductible for the year;
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. A CBE requiring further diagnosis (see I. C. 1.);
 - b. a 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** should be reported as:
 - a. Normal exam
 - b. Benign findings
 - c. Bloody/serous nipple discharge
 - d. Discrete palpable mass—suspicious for cancer
 - e. Nipple/areolar scaliness
 - f. Skin dimpling/retraction
2. CBE should report whether there are breast implants; however, this finding would be categorized as a “Benign finding” if no other abnormalities were found.
3. 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.
4. **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)
5. **Breast composition on mammogram** should be described for all patients using the following patterns:
 - a. The breast is almost entirely fat (<25% glandular)
 - b. There are scattered fibroglandular densities (approximately 25-50% glandular)

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

- c. The breast tissue is heterogeneously dense, which could obscure detection of small masses (approximately 51-75% glandular)
- d. The breast tissue is extremely dense. This may lower the sensitivity of mammography (>75% glandular).

Ref. 2003 ACR BI-RADS[®] Atlas

- 6. **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.
- 7. 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 B.** 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. Magnetic Resonance Imaging (MRI)
 - a. The DHMH BCCP **will not reimburse** for MRI for breast cancer **screening**.

- b. If recommended by the managing physician, the expanded diagnostic BCCP **will reimburse** for a MRI of the breast for:
 - i. Extent of disease in the ipsilateral breast in patients with a recent diagnosis of breast cancer;
 - ii. Screening of the contralateral breast in women with a current, newly diagnosed, unilateral breast cancer;
 - iii. Evaluation of patients undergoing current neoadjuvant chemotherapy for breast cancer;
 - iv. Positive margins after surgery for breast malignancy; or
 - v. Chest wall invasion suspected.

- c. 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 to a surgical consult of “benign findings”);
 - ii. Problem solving for inconclusive clinical or mammographic findings; or
 - iii. Evaluation of silicone breast implant integrity.

- 2. The BCCP will pay 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.

- 3. The BCCP will pay for a maximum of two consults with the same surgeon in one year for the same benign breast problem.

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Attachment A

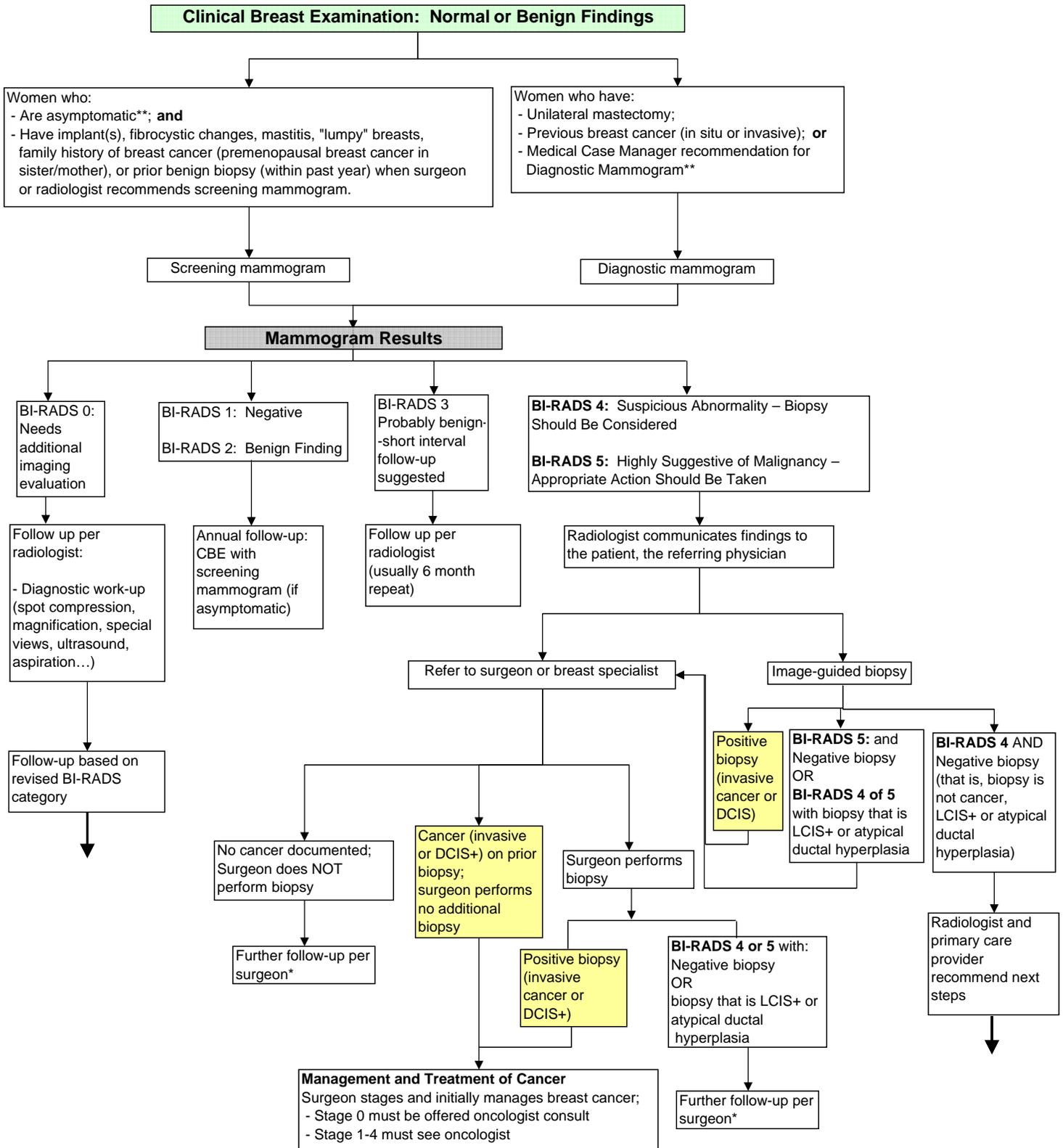
Flow Charts of the Maryland Breast and Cervical Cancer Program:

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**

**I. Management of Clinical Breast Exam and Mammogram Results:
Normal/Benign Clinical Breast Exam**



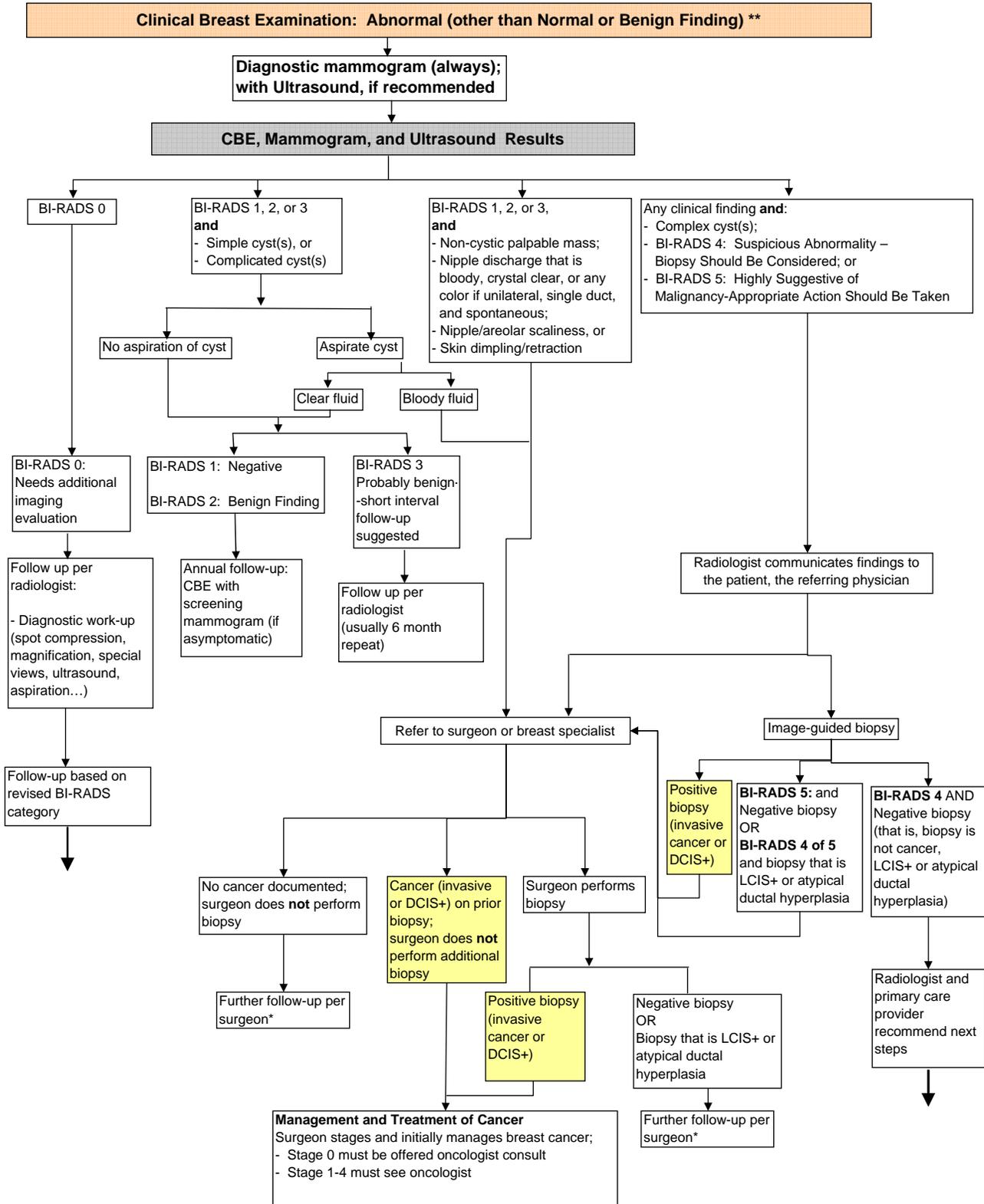
* The BCCP will reimburse for a maximum of two consults per year to the same surgeon for the same benign breast finding

** A woman with persistent, unexplained, localized pain in the breast should be evaluated by a breast specialist or surgeon (see Attachment A, II. B. 2.)

+ DCIS: Ductal carcinoma in situ

LCIS: Lobular carcinoma in situ

II. Management of Clinical Breast Exam and Mammogram Results: Abnormal Clinical Breast Exam



* The BCCP will reimburse for a maximum of two consults per year to the same surgeon for the same benign breast finding

** "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 or retraction

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